MegaGen Implant Co., Ltd.
% You Kim
Chief Researcher
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REPUBLIC OF KOREA

June 22, 2021

Re: K210161
Trade/Device Name: AnyOne Onestage Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 20, 2021
Received: May 24, 2021

Dear You Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210161

Device Name
AnyOne Onestage Implant System

Indications for Use *(Describe)*
The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:
-Delayed loading.
-Immediate loading when good
primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for K210161

Date: June 22, 2021

1. Applicant / Submitter

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3. Device

- Trade Name: AnyOne Onestage Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Endosseous dental implant
- Classification Product Code: DZE
- Secondary Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3640

4. Predicate Device

- **Primary Predicate Device:**
  K182448- AnyRidge Octa 1 Implant System

- **Reference Devices:**
  K052369 - ExFeel Dental Implant System
  K150537 - MiNi Internal Implant System
  K123988 - AnyOne Internal Implant System
  K160670 - ET US SS Prosthetic System
  K171027 - Dentis Dental Implant System
  K192614 - Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment
  K182091 - Osstem Abutment System

5. Description

- AnyOne Onestage Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients and consists of fixtures and abutments. The dental implants which used in conjunction with other prosthesis restore the lost chewing ability and improve the appearance.

- AnyOne Onestage Fixture is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method. It is placed in the anterior or posterior site of maxillary or mandibular jawbone considering bone quality and bone quantity. The fixtures have Octa connection, and various cuff height with consideration for soft tissue level (gingival height). These fixtures can be used the one-stage and two-stage surgical procedure. This device is a tissue level implant.

- Dental prosthesis is an abutment of a dental implant system and connecting elements between the dental implant and the restoration. The abutment is fixed to the implant and is permanently or temporary in contact with the gum in the surgical cavity. These abutments are made of Ti-6Al-4V ELI, Gold alloy, CCM alloy and POM, and intended to be placed on the fixture allows single & multiple prosthetic restorations to restore a patient's chewing function.

- The proposed AnyOne Onestage Implant System is consisted of the following components. For reference, all the subject device in this submission are to be added Megagen's existing implant and prosthetic portfolio which had been FDA cleared.

Content			
1. Fixture Products	**AnyOne Onestage Fixture**	Description	AnyOne Onestage Fixture is a substructure of a dental implant system made of titanium and have the interface connection for Internal Octa. It is used in conjunction with other prosthetic and restore lost chewing ability, improve appearance.
		Material	CP Ti Grade 4 (ASTM F67-13)
		Dimension (Diameter & Length)	Ø 3.9 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 4.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 4.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 5.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm
		Gingival (Cuff) Height	1.2, 1.8, 2.2 mm
2. Closing Screw & Cover Screw & Healing Abutment	**Closing Screw**	Description	The Closing Screw is used in conjunction with fixture for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 6.0 mm
		Gingival (Cuff) Height	1.5mm
		Angulation	Straight
	Cover Screw	Description	The Cover Screw is used in conjunction with fixture for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.85 x 7.0 mm
		Gingival (Cuff) Height	1.5mm
		Angulation	Straight
	Healing Abutment	Description	The Healing Abutment is used in conjunction with fixture and helps to form suitable emergence profile during period of gingival healing.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.5 x 6.5, 7.5, 8.5 mm
		Gingival (Cuff) Height	2.0, 3.0, 4.0 mm
		Angulation	Straight
3. Fixture Level Prosthesis	**Multi Post**	Description	The Multi Post is used in conjunction with fixture to provide support for cement retained type final prosthesis. It is connected to the Fixture using Multi Post Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.5 x 8.7 mm

		Gingival (Cuff) Height	1.0 mm
		Post Height	5.5 mm
		Angulation	Straight
	Multi Post Cap	Description	The Multi Post Cap is used to protect Multi Post, minimizes discomfort of oral cavity and relieve feeling of irritation and protect until the prosthesis is produced after the impression is taken.
		Material	POM
		Dimension (Diameter & Length)	Ø 5.9 x6.5 mm
		Post Height	5.5 mm
	EZ Post Abutment	Description	The EZ Post Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis. It is connected to the Fixture using Multi Post Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 6.2, 7.2,10) 7.7, 8.2, 8.7, 9.2, 9.7, 10.2, 10.7, 11.2, 12.2 mm
		Gingival (Cuff) Height	0.0, 1.0, 2.0, 3.0 mm
		Post Height	4.0, 5.5, 7.0 mm
		Angulation	Straight
	Angled Abutment	Description	The Angled Abutment is used in conjunction with fixture and used for correcting the prosthetic angulation of implant. It is connected to the Fixture using Abutment Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.7 x 9.0 mm
		Post Height	6.5 mm
		Angulation	15°, 25°
	Gold Abutment	Description	The Gold Abutment is used in conjunction with fixture and used for fabrication of abutment for either screw or cement retained restorations by casting with precious metal alloy (Gold alloy). It is connected to the Fixture using Multi Post Screw.
		Material	Body: Gold Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 5.5 x 13.65 mm
		Gingival (Cuff) Height	1.5 mm
		Post Height	10.0 mm
		Angulation	Straight
	CCM Abutment	Description	The CCM Abutment is used in conjunction with fixture and used for fabrication of abutment for either screw or cement retained restorations by casting with non-precious metal alloy (Co-Cr-Mo alloy). It is connected to the Fixture using Multi Post Screw.
		Material	Body: Co-Cr-Mo Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 5.5 x 13.65 mm
		Gingival (Cuff) Height	1.5 mm
		Post Height	10.0 mm
		Angulation	Straight
	Multi Post Screw	Description	The Multi Post Screw is used for connecting Fixture to Multi Post, EZ Post Abutment, Gold Abutment or CCM Abutment
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.5 x 8.1 mm
	Abutment Screw	Description	The Abutment Screw is used for connecting Fixture to Angled Abutment.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.6 x 5.5 mm
4.Abutment Level Prosthesis	**Solid Abutment**	Description	The Solid Abutment is used in conjunction with fixture to provide support for final prosthesis, and used in cement retained restoration only. It is connected to the Fixture by its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension	Ø 3.5 x 9.0, 10.5, 12.0 mm

		(Diameter & Length)	
		Post Height	4.0, 5.5, 7.0 mm
		Angulation	Straight
	Solid Cap	Description	The Solid Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.
		Material	POM
		Dimension (Diameter & Length)	Ø 5.7 x 6.5, 8.0, 9.5 mm
		Post Height	4.0, 5.5, 7.0 mm
	Solid Post Abutment	Description	The Solid Post Abutment is used in conjunction with fixture to provide support for final prosthesis, and used in cement retained restoration only. It is connected to the Fixture by its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.9 x 9.5, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5, 14.5 mm
		Gingival (Cuff) Height	1.0, 2.0, 3.0 mm
		Post Height	4.0, 5.5, 7.0 mm
		Angulation	Straight
	Solid Post Cap	Description	The Solid Post Cap is used for protecting a Solid Post Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.
		Material	POM
		Dimension (Diameter & Length)	Ø 5.3 x 6.5, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 10.5, 11.5 mm
		Gingival (Cuff) Height	1.0, 2.0, 3.0 mm
		Post Height	4.0, 5.5, 7.0 mm
	Octa Abutment	Description	The Octa Abutment is used in conjunction with fixture for fabricating screw-retained prosthesis. It is connected to the Fixture by its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 6.5 mm
		Post Height	1.5 mm
		Angulation	Straight
	Healing Cap	Description	The Healing Cap is used for protecting Octa Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Octa Abutment using Abutment Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.2 x 4.0 mm
	Temporary Cylinder	Description	The Temporary Cylinder is used in conjunction with Octa Abutment to provide support for provisional restoration. It is connected to the Octa Abutment using Abutment Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.0 x 10.0 mm
		Post Heights	7.0 mm
		Angulation	Straight
	EZ Post Cylinder	Description	The EZ Post Cylinder is used in conjunction with Octa Abutment to provide support for cement and screw type final prosthesis. It is connected to the Octa Abutment using Abutment Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.0 x 5.5, 7.0 mm
		Post Heights	5.5, 7.0 mm
		Angulation	Straight
	Gold Cylinder	Description	The Gold Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with precious metal alloy (Gold alloy). It is connected to the Octa Abutment using Abutment Screw.
		Material	Body: Gold Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 5.1 x 12.0 mm
		Post Heights	10.0 mm
		Angulation	Straight

	CCM Cylinder	Description	The CCM Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo alloy). It is connected to the Octa Abutment using Abutment Screw.
		Material	Body: Gold Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 5.1 x 12.0 mm
		Post Heights	10.0 mm
		Angulation	Straight
	Abutment Screw	Description	The Abutment Screw is used for connecting the Octa Abutment to the Healing Cap, Temporary Cylinder, EZ Post Cylinder, Gold Cylinder or CCM Cylinder.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.5 x 4.85 mm
5.Overdenture Prosthesis	**Meg-Loc Abutment**	Description	The Meg-Loc Abutment is used in conjunction with fixture and intended to be connected to an overdenture to allow its insertion and removal with its attachment (K151789). It is connected to the Fixture using its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.89 x 7.45, 7.95, 8.95, 9.95, 10.95, 11.95, 12.95, 13.95 mm
		Gingival (Cuff) Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8 mm
		Post Height	1.5 mm
		Angulation	Up to 20°
	Meg-Ball Abutment	Description	The Meg-Ball Abutment is used in conjunction with fixture and intended to be connected to an overdenture to allow its insertion and removal with its attachment (K192614). It is connected to the Fixture using its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Head Diameter & Head Length)	Ø 2.25 x 4.15 mm
		Dimension (Diameter & Length)	Ø 3.5 x 10.1, 10.6, 11.6, 12.6, 13.6, 14.6, 15.6, 16.6 mm
		Gingival (Cuff) Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8 mm
		Post Height	4.15 mm
		Angulation	Up to 15°
	Meg-Magnet Abutment	Description	The Meg-Magnet Abutment is used in conjunction with fixture and intended to be connected to an overdenture to allow its insertion and removal using the magnetic force of magnet attachment. It is connected to the Fixture using its threaded part.
		Material	Stainless Steel (ASTM F899-20)
		Dimension (Diameter & Length)	Ø 4.5 x 6.20, 6.25, 6.75, 7.20, 7.75, 8.20, 8.75, 9.20, 9.75, 10.20, 10.75, 11.20, 11.75, 12.20, 12.75 mm Ø 5.0 x 6.20, 6.25, 6.75, 7.20, 7.75, 8.20, 8.75, 9.20, 9.75, 10.20, 10.75, 11.20, 11.75, 12.20, 12.75 mm
		Gingival (Cuff) Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8 mm
		Angulation	Straight
	Magnet	Description	The Magnet is used in fixed overdenture restorations and applied with Meg-Magnet Abutment to stabilize the overdenture using its magnetic force.
		Material	Stainless Steel (ASTM F899-20)
		Dimension (Diameter & Length)	Ø 4.5 x 2.2 mm Ø 5.0 x 2.2 mm
	Meg-Rhein Abutment	Description	The Meg-Rhein Abutment is used in conjunction with fixture and intended to be connected to an overdenture to allow its insertion and removal with its attachment (K171409). It is connected to the Fixture using its threaded part.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 7.45, 9.15, 11.15, 13.15 mm
		Gingival (Cuff) Height	0.3, 2.0, 4.0, 6.0mm
		Post Height	1.7 mm
		Angulation	Straight

[Note. 1] Some of devices described in this submission had been FDA cleared with **K052369** and **K123988**, but it is being submitted to change their identifier with modification of product name or material as followings. The changes are explained not affecting substantial equivalence in this 510(k) Submission.

No.	Predicate Device			Subject Device		Change
	510(k) No.	Product Name	Material	Product Name	Material	
1	K052369	Closing Screw	CP Ti Grade 3	Closing Screw	Ti-6Al-4V ELI	- Material
2	K052369	Cover Screw	CP Ti Grade 3	Cover Screw	Ti-6Al-4V ELI	- Material
3	K052369	Healing Abutment	CP Ti Grade 3	Healing Abutment	Ti-6Al-4V ELI	- Material
4	K052369	ExFeel Internal Multi-mount	CP Ti Grade 3	Multi Post	Ti-6Al-4V ELI	- Product Name - Material
5	K052369	ExFeel Internal Multi-mount Cap	No Change	Multi Post Cap	No Change	- Product Name
6	K052369	ExFeel Internal Screw	No Change	Multi Post Screw	No Change	- Product Name
7	K052369	Solid Abutment	CP Ti Grade 3	Solid Abutment	Ti-6Al-4V ELI	- Material
8	K052369	Solid Protect Cap	No Change	Solid Cap	No Change	- Product Name
9	K123988	Octa Healing Cap	No Change	Healing Cap	No Change	- Product Name
10	K123988	Temporary Cylinder	CP Ti Grade 4	Temporary Cylinder	Ti-6Al-4V ELI	- Material
11	K123988	EZ Post Cylinder	CP Ti Grade 4	EZ Post Cylinder	Ti-6Al-4V ELI	- Material
12	K123988	Octa Abutment Screw	No Change	Abutment Screw	No Change	- Product Name

[Note. 2] Some of overdenture prosthesis described in this submission had been FDA cleared with **K192614**, but it is being submitted to change their identifier with modification of surface treatment or compatible implant system as followings. The changes are explained not affecting substantial equivalence in this 510(k) Submission.

No.	Predicate Device				Subject Device			Change
	510(k) No.	Product Name	Surface Treatment	Implant System	Product Name	Surface Treatment	Implant System	
1	K192614	Meg-Loc Abutment	Machined	ExFeel Dental Implant System (K052369)	Meg-Loc Abutment	TiN Coating	AnyOne Onestage Implant System	- Surface Treatment - Implant System
2	K192614	Meg-Ball Abutment	No Change	ExFeel Dental Implant System (K052369)	Meg-Ball Abutment	No Change	AnyOne Onestage Implant System	- Implant System
3	K192614	Meg-Magnet Abutment	No Change	ExFeel Dental Implant System (K052369)	Meg-Magnet Abutment	No Change	AnyOne Onestage Implant System	- Implant System

6. Indication for use

The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:
-Delayed loading.
-Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.

7. Basis for Substantial Equivalence

The AnyOne Onestage Implant System is substantially equivalent to the predicate devices in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design.

The Indications for Use for the subject devices is identical to the primary predicate, K182448.

In order to demonstrate the difference in design does not raise any new issues, the performance test on the subject and predicate device have been performed in consideration of the worst case according to 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to figure out the physical property. The test result supports the substantial equivalence to the predicate devices.

Based on the comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate devices.

AnyOne Onestage Fixture

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**AnyOne Onestage Fixture** For AnyOne Onestage Implant System	**AnyRidge Octa 1 Fixture** For AnyRidge Octa 1 Implant System	**ExFeel Internal Fixture** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	3.9, 4.3, 4.8, 5.3 mm	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5mm	3.5, 4.1, 4.8 mm
Length	7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm	7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm	7.0, 8.5, 10.0, 11.5, 13.0 mm
Gingival (Cuff) Height	1.2, 1.8, 2.2 mm	N/A	2.2 mm
Implant-to Abutment Connection	Internal Octa	Internal Octa	Internal Octa
Material	CP Ti Grade 4 (ASTM F67-13)	CP Ti Grade 4 (ASTM F67-13)	CP Ti Grade 4 (ASTM F67-13)
Single Use	Yes	Yes	Yes
Surface Treatment	Sand-blasted, Large grit, Acid-etched (SLA) and Partial Anodizing in upper part	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted (RBM) and Partial Anodizing in upper part
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf Life	5 years	5 years	5 years
Feature	- Straight / Tapered body shape - cutting edge with self-tapping - 0.8mm thread pitch	- Straight / Tapered body shape - cutting edge with self-tapping - 0.8mm thread pitch	- Straight / Root form shape - cutting edge with self-tapping - 1.25mm thread pitch
Principle of Operation	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	It is a root form fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device.

Indication for use, Design, Connection, Material, Single Use, Sterilization, Shelf Life, Feature and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device.

- Diameter & Length

  The Diameter and Length of subject device is slightly different with predicate device but all the dimensions of subject device lie within the range of predicate device and reference device.

- Gingival (Cuff) Height

  The subject device has cuff height with consideration for soft tissue level while the predicate device is not applicable but the reference device has a cuff height. Also, the total length of subject device including the cuff height lie within the range of predicate device and reference device, and it does not cause a matter in substantial equivalence since

the size of cuff height is very minor, the cuff height provides good gingival adaptation and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Surface Treatment

The general surface treatment of subject device is same as predicate device with SLA method, but the subject device is additionally treated with anodizing in upper part for good visibility of cuff height. The substantially equivalent can be explained with reference device which has same surface treatment for anodizing.

3. Discussion

- The proposed AnyOne Onestage Fixture and predicate device have common in all the items in the comparison chart except the Diameter, Length, Gingival (Cuff) Height and Surface Treatment. These differences are explained not affecting on the substantial equivalence, but the fatigue test was performed on the subject device and predicate device to confirm the substantial equivalence, with combination of the worst case design fixture and abutment, according to "ISO 14801" and "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment". The test result supports that the subject device is substantially equivalent to the predicate device and the differences are not affecting the substantial equivalence. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Closing Screw

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**Closing Screw** For AnyOne Onestage Implant System	**Cover Screw** For AnyRidge Octa 1 Implant System	**Closing Screw** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	3.5 mm	3.0, 3.7, 5.0, 6.0 mm	3.5 mm
Total Length	6.0 mm	6.6, 7.1 mm	6.0 mm
Gingival (Cuff) Height	1.5 mm	0.5, 1.0 mm	1.5 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Principle of Operation	The Closing Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	The Closing Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Gingival Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed Closing Screw had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of material. Therefore, the proposed Closing Screw and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Cover Screw

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**Cover Screw** For AnyOne Onestage Implant System	**Cover Screw** For AnyRidge Octa 1 Implant System	**Cover Screw** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	4.85 mm	3.0, 3.7, 5.0, 6.0 mm	4.85 mm
Total Length	7.0 mm	6.6, 7.1 mm	7.0 mm
Gingival (Cuff) Height	1.5 mm	0.5, 1.0 mm	1.5 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Principle of Operation	The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device.
   - Indication for use, Design, Diameter, Total Length, Gingival Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation
2. **Differences**
   The subject device has the different characteristic for the followings compared to the reference device.
   - Material
     The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.
3. **Discussion**
   - The proposed Cover Screw had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of material. Therefore, the proposed Cover Screw and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Healing Abutment

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**Healing Abutment** For AnyOne Onestage Implant System	**Healing Abutment** For AnyRidge Octa 1 Implant System	**Healing Abutment** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	5.5 mm	3.2, 4.2, 5.2, 6.2 mm	5.5 mm
Total Length	6.5, 7.5, 8.5 mm	8.6, 9.6, 10.6, 11.6, 12.6, 13.6, 14.6, 15.6 mm	6.5, 7.5, 8.5 mm
Gingival (Cuff) Height	2.0, 3.0, 4.0 mm	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 mm	2.0, 3.0, 4.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Principle of Operation	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Gingival Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed Healing Abutment had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of material. Therefore, the proposed Healing Abutment and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Multi Post

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**Multi Post** For AnyOne Onestage Implant System	**EZ Post Abutment** For AnyRidge Octa 1 Implant System	**ExFeel Internal Multi-mount** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	5.5 mm	4.0, 5.0, 6.0, 7.0 mm	5.5 mm
Total Length	8.7 mm	7.85 - 16.35 mm	8.7 mm
Gingival (Cuff) Height	1.0 mm	0.8, 1.8, 2.8, 3.8, 4.8 mm	1.0 mm
Post Height	5.5 mm	4.0, 5.5, 7.0 mm	5.5 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Octa	Internal Octa, Internal Non-Octa	Internal Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Multi Post is a superstructure which is connected to the Fixtures using the Multi Post Screw. It replaces the functions of the missing teeth as a dental abutment.	The EZ Post Abutment is a superstructure which is connected to the Fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The ExFeel Internal Multi-mount is a superstructure which is connected to the Fixtures using the ExFeel Internal Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Gingival Height, Post Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed Multi Post had been FDA cleared under K052639 with product name of 'ExFeel Internal Multi-mount', but it is being submitted to change their identifier with modification of product name and material. Therefore, the proposed Multi Post and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Multi Post Cap

	Subject Device	Reference Device
510(k) No.	K210161	K052369
Device Name (Compatible Implant System)	**Multi Post Cap** For AnyOne Onestage Implant System	**ExFeel Internal Multi-mount Cap** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design		
Diameter (Ø)	5.9 mm	5.9 mm
Total Length	6.5 mm	6.5 mm
Post Height	5.5 mm	5.5 mm
Material	POM	POM
Surface Treatment	N/A	N/A
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The multi post cap is used to relieve feeling of irritation and protect until the prosthesis is produced after the impression is taken.	The multi post cap is used to relieve feeling of irritation and protect until the prosthesis is produced after the impression is taken.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Post Height, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

- N/A

3. Discussion

- The proposed Multi Post Cap had been FDA cleared under K052639 with product name of 'ExFeel Internal Multi-mount Cap', but it is being submitted to change their identifier with modification of product name only. Therefore, the proposed Multi Post Cap and reference device have common in all the items in the comparison chart. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

EZ Post Abutment

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**EZ Post Abutment** For AnyOne Onestage Implant System	**EZ Post Abutment** For AnyRidge Octa 1 Implant System	**Solid Abutment** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	4.8 mm	4.0, 5.0, 6.0, 7.0 mm	3.5 mm
Total Length	6.2, 7.2, 7.7, 8.2, 8.7, 9.2, 9.7, 10.2, 10.7, 11.2, 12.2 mm	7.85, 8.85, 9.35, 9.85, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm	9.0, 10.5, 12.0 mm
Gingival (Cuff) Height	0.0, 1.0, 2.0, 3.0 mm	1.0, 2.0, 3.0, 4.0, 5.0 mm	0.0 mm
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Anodizing	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The EZ Post Abutment is a superstructure which is connected to the Fixtures using the Multi Post Screw. It replaces the functions of the missing teeth as a dental abutment.	The EZ Post Abutment is a superstructure which is connected to the Fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Solid Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the predicate device.
   - Indication for use, Design, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. **Differences**

   The subject device has the different characteristic for the followings compared to the predicate device.
   - Diameter

     The diameter of subject device is slightly different with predicate device, but the Diameters of subject device lie within the range of predicate device.
   - Total Length

     The Length of subject device is slightly different with predicate device, but has same Gingival Height and Post Height with predicate & reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.

- Gingival (Cuff) Height
  The subject device includes the models do not have the cuff height (0.0mm) while the predicate device has cuff height from 1.0 mm to 5.0mm. However, the reference device is not applicable the cuff height as the subject device. The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

3. <u>Discussion</u>

- The proposed EZ Post Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed EZ Post Abutment and predicate device have common in all the items in the comparison chart except the Diameter and Total Length. The size differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Angled Abutment

	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K182448	K150537	K182448
Device Name (Compatible Implant System)	**Angled Abutment** For AnyOne Onestage Implant System	**Angled Abutment** For AnyRidge Octa 1 Implant System	**Angled Abutment** For MiNi Internal Implant System	**Multi-unit Angled Abutment** For AnyRidge Octa 1 Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.
Design				
Diameter (Ø)	3.7 mm	4.0, 5.0, 6.0, 7.0mm	3.5 mm	4.8 mm
Total Length	9.0 mm	10.85, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm	11.7, 12.7, 13.7 mm	6.8, 7.48, 7.8, 8.48, 8.5, 8.8, 8.98, 9.5, 9.98, 10.5 mm
Gingival (Cuff) Height	N/A	0.8, 1.8, 2.8, 3.8, 4.8mm	2.5, 3.5, 4.5 mm	2.3, 3.3, 4.3mm
Post Height	6.5 mm	7.0 mm	7.0 mm	2.2 mm
Angulation	15°, 25°	15°, 25°	15°	17°, 30°
Connection Interface	Internal Octa	Internal Octa	Internal Hex	Internal Octa, Internal Non-Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing, Machined	Anodizing	Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Angled Abutment is a superstructure which is connected to the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Angled Abutment is a superstructure which is connected to the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Angled Abutment is a superstructure which is connected to the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Multi-unit Angled Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Multi-unit Abutment screw for aid in prosthetic rehabilitation.
Substantial Equivalence Discussion				
1. Similarities The subject device has the same characteristic for the followings compared to the predicate device. - Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation				

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device.

- Diameter & Total Length

  The diameter and total length of subject device is slightly different with predicate device, but all the dimensions of subject device lie within combined range of predicate & reference devices.

- Gingival (Cuff) Height & Post Height

  The subject device is not applicable the cuff height while the predicate device has the cuff height. That's why the total length of subject device is slightly shorter than predicate device. However, it can be replaced with Fixture's cuff height connecting the proposed fixture and angled abutment.

  The Post Height of subject device is slightly different with predicate device, but it lies within combined range of predicate & reference devices.

  The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

3. Discussion

- The proposed Angled Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared as with predicate device. Therefore, the proposed Angled Abutment and predicate device have common in all the items in the comparison chart except the Diameter, Total Length, Gingival (Cuff) Height and Post Height. These size differences are explained not affecting on the substantial equivalence, but the fatigue test was performed on the subject & predicate devices to confirm the substantial equivalence. The subject device, Angled Abutment has been selected as the representative specimen in this submission under the consideration of worst case in accordance with 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The test result supports that the subject device is substantially equivalent to the predicate device and the differences are not affecting the substantial equivalence. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Gold Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K123988	K123988
Device Name (Compatible Implant System)	**Gold Abutment** For AnyOne Onestage Implant System	**Gold Abutment** For AnyOne Internal Implant System	**Gold Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.5 mm	4.5 mm	4.0, 4.8, 5.1, 6.0 mm
Total Length	13.65 mm	15.7 mm	12.0, 13.0 mm
Gingival (Cuff) Height	1.5 mm	1.0 mm	2.0, 3.0 mm
Post Height	10.0 mm	11.0 mm	10.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Octa, Non-Octa	Internal Hex, Non-Hex	Internal Octa, Non-Octa Internal Hex, Non-Hex
Material	Body: Gold Alloy / Sleeve: POM	Body: Gold Alloy / Sleeve: POM	Body: Gold Alloy / Sleeve: POM
Surface Treatment	N/A	N/A	N/A
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Gold Abutment is used in conjunction with fixture to provide support for screw or cement type final prosthesis by casting with gold alloy. It is connected to the Fixture with Multi Post Screw.	The Gold Abutment is used in conjunction with Fixture to provide support for screw type final prosthesis by casting with gold alloy. It is connected to the Fixture using the Screw.	The Gold Cylinder is used in conjunction with Octa Abutment and Multi-unit Abutment to provide support for screw type final prosthesis by casting with gold alloy. It is connected to the Abutment using the Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Angulation, Material, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter, Total Length, Gingival (Cuff) Height and Post Height

  The dimension of subject device is slightly different with reference device 1 but the dimension of subject device lies within combined range of reference device 1 & 2. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
- Connection Interface

  The subject device has Internal Octa connection while the reference device 1 has Internal Hex connection, but has same connection structure as reference device 2. Also, both feature of Octa and Hex provides anti-rotational feature and multiple predicate & reference devices for Octa / Non-Octa are already presented in the other component comparison charts.

3. Discussion

- The proposed Gold Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Gold Abutment and reference devices have common in all the items in the comparison chart except the Diameter, Total Length, Gingival (Cuff) Height and Post Height. These size differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference devices.

CCM Abutment

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K123988
Device Name (Compatible Implant System)	**CCM Abutment** For AnyOne Onestage Implant System	**CCM Abutment** For AnyRidge Octa 1 Implant System	**CCM Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.5 mm	3.8 mm	4.0, 5.1, 6.0 mm
Total Length	13.65 mm	14.65 mm	12.0 mm
Gingival (Cuff) Height	1.5 mm	1.0 mm	2.0 mm
Post Height	10.0 mm	11.6 mm	10.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	Internal Octa, Non-Octa
Material	Body: Co-Cr-Mo alloy Sleeve: POM	Body: Co-Cr-Mo Alloy Sleeve: POM	Body: Co-Cr-Mo Alloy Sleeve: POM
Surface Treatment	N/A	N/A	N/A
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The CCM Abutment is used in conjunction with fixture to provide support for screw or cement type final prosthesis by casting with CCM alloy. It is connected to the Fixture with Multi Post Screw.	The CCM Abutment is used in conjunction with Fixture to provide support for screw type final prosthesis by casting with CCM alloy. It is connected to the Fixture using the Screw.	The CCM Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with CCM alloy. It is connected to the Abutment using the Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device.

- Indication for use, Design, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device.

- Diameter, Total Length, Gingival (Cuff) Height and Post Height

The dimension of subject device is slightly different with predicate device but the dimension of subject device lies within combined range of predicate & reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.

3. Discussion

- The proposed CCM Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed CCM Abutment and predicate device have common in all the items in the comparison chart except the Diameter, Total Length, Gingival (Cuff) Height and Post Height. These size differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Multi Post Screw

	Subject Device	Reference Device
510(k) No.	K210161	K052369
Device Name (Compatible Implant System)	**Multi Post Screw** For AnyOne Onestage Implant System	**ExFeel Internal Screw** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design		
Diameter (Ø)	2.5 mm	2.5 mm
Total Length	8.1 mm	8.1 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Multi Post Screw is used for connecting the Multi Post, EZ Post Abutment, Gold Abutment and CCM Abutment to the Fixture.	The ExFeel Internal Screw is used for connecting the ExFeel Internal Multi-mount, EZ Post Abutment, Gold Abutment and CCM Abutment to the Fixture.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

- N/A

3. Discussion

- The proposed Multi Post Screw had been FDA cleared under K052639 with product name of 'ExFeel Internal Screw', but it is being submitted to change their identifier with modification of product name only. Therefore, the subject device and reference device have common in all the items in the comparison chart.

  On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Solid Abutment

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K052369
Device Name (Compatible Implant System)	**Solid Abutment** For AnyOne Onestage Implant System	**EZ Post Abutment** For AnyRidge Octa 1 Implant System	**Solid Abutment** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design			
Diameter (Ø)	3.5 mm	4.0, 5.0, 6.0, 7.0 mm	3.5 mm
Total Length	9.0, 10.5, 12.0 mm	7.85 - 16.35 mm	9.0, 10.5, 12.0 mm
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Octa, Internal Non-Octa	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Solid Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.	The EZ Post Abutment is a superstructure which is connected to the Fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Solid Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed Solid Abutment had been FDA cleared under K052639, but it is being submitted to change their identifier with modification of material only. Therefore, the proposed Solid Abutment and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Solid Cap

	Subject Device	Reference Device
510(k) No.	K210161	K052369
Device Name (Compatible Implant System)	**Solid Cap** For AnyOne Onestage Implant System	**Solid Protect Cap** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.
Design		
Diameter (Ø)	5.7 mm	5.7 mm
Total Length	6.5, 8.0, 9.5 mm	6.5, 8.0, 9.5 mm
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm
Material	POM	POM
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Solid Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.	The Solid Protect Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the reference device.
   - Indication for use, Design, Diameter, Total Length, Post Height, Material, Single Use, Sterilization and Principle of Operation.
2. **Differences**
   - N/A
3. **Discussion**
   - The proposed Solid Cap had been FDA cleared under K052639 with product name of 'Solid Protect Cap', but it is being submitted to change their identifier with modification of product name only. Therefore, the subject device and reference device have common in all the items in the comparison chart. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Solid Post Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K123988	K160670
Device Name (Compatible Implant System)	**Solid Post Abutment** For AnyOne Onestage Implant System	**Solid Abutment** For AnyOne Internal Implant System	**Solid Abutment** For ET US SS Prosthetic System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region..	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	**ET System** The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures. **US/SS System** The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.
Design			
Diameter (Ø)	4.9 mm	4.0, 4.5, 5.5, 6.5 mm	3.5, 4.3 mm
Total Length	9.5, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5, 14.5 mm	11.2, 12.1 12.7, 13.2, 13.7, 14.2, 14.7, 15.2, 15.7, 16.2, 16.7, 17.2, 17.7, 18.7 mm	9.5, 9.8, 11, 11.3, 12.5, 12.8 mm
Gingival (Cuff) Height	1.0, 2.0, 3.0 mm	1.0, 1.5 2.5, 3.5, 4.5, 5.5mm	Not known
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0mm	Not known
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Titanium Alloy
Surface Treatment	Machined	Machined	Not known
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Solid Post Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.	The Solid Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.	The Solid Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter & Gingival (Cuff) Heights

  The diameter and Gingival (Cuff) Height of subject device is slightly different with reference devices, but these dimensions lie within the range of reference device 1.
- Total Length

  The Total Length of subject device is slightly different with reference devices, but it lies within combined range of reference device 1&2, and has similar Gingival Height and same Post Height with reference device 1. Also, it does not cause a matter in substantial equivalence since the size difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

- The proposed Solid Post Abutment and reference devices have common in all the items in the comparison chart except the Diameter, Total Length and Gingival (Cuff) Height. These size differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference devices.

Solid Post Cap

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K052369	K123988
Device Name (Compatible Implant System)	**Solid Post Cap** For AnyOne Onestage Implant System	**Solid Protect Cap** For ExFeel Dental Implant System	**Comfort Cap** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.3 mm	5.7 mm	4.0, 4.5, 5.5, 6.5 mm
Total Length	6.5, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 10.5, 11.5 mm	6.5, 8.0, 9.5 mm	5.4, 5.5, 5.6, 6.9, 7.0, 7.1, 8.4, 8.5, 8.6 mm
Gingival (Cuff) Height	1.0, 2.0, 3.0 mm	N/A	N/A
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm
Material	POM	POM	POM
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Solid Post Cap is used for protecting a Solid Post Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.	The Solid Protect Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.	The Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Post Height, Material, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter, Total Length and Gingival (Cuff) Height

  The diameter of subject device is slightly different with reference device 1, but it lies within combined range of reference device 1&2.

  The total length is slightly different with reference device 1, but has same post height with reference device 1&2. And, the subject device has the cuff height corresponding to the its compatible abutment, while the reference devices are not applicable, but these do not cause a matter in substantial equivalence since the size difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

- The proposed Solid Post Cap and reference devices have common in all the items in the comparison chart except the Diameter, Total Length and Gingival (Cuff) Height. These size differences are explained not affecting on the substantial equivalence. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference devices.

Octa Abutment

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K171027
Device Name (Compatible Implant System)	**Octa Abutment** For AnyOne Onestage Implant System	**Octa Abutment** For AnyRidge Octa 1 Implant System	**Octa Abutment** Dentis Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Dentis Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Design			
Diameter (Ø)	3.5 mm	3.8, 4.8, 5.8 mm	3.5, 4.3
Total Length	6.5 mm	7.85, 8.85, 9.35, 9.85, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.85 mm	7.0,7.3 mm
Gingival (Cuff) Height	N/A	1.0, 2.0, 3.0, 4.0, 5.0 mm	Not known
Post Height	1.5 mm	1.5 mm	Not known
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Anodizing	Not known
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Octa Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation. This device is a two piece abutment that is always used with a cylinder (such as the Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, or CCM Cylinder) to form the final abutment.	The Octa Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation. This device is a two piece abutment that is always used with a cylinder (such as the Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, or CCM Cylinder) to form the final abutment.	The Octa Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant by its threaded part for aid in prosthetic rehabilitation.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device.

- Indication for use, Design, Post Height, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device.

- Diameter, Total Length and Gingival (Cuff) Height

The diameter of subject device is slightly different with predicate device, but it lies within combined range of predicate & Reference devices. The total length is slightly different with predicate device, but has same post height with predicate devices. The subject device is not applicable the cuff height while the predicate device has the cuff height. That's why the total length of subject device is slightly shorter than predicate device. However, it can be replaced with Fixture's cuff height connecting the proposed fixture and octa abutment. The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

3. Discussion

- The proposed Octa Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Octa Abutment and predicate device have common in all the items in the comparison chart except the Diameter, Total Length and Gingival (Cuff) Height. These size differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Healing Cap

	Subject Device	Reference Device
510(k) No.	K210161	K123988
Device Name (Compatible Implant System)	**Healing Cap** For AnyOne Onestage Implant System	**Octa Healing Cap** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design		
Diameter (Ø)	5.2 mm	5.2 mm
Total Length	4.0 mm	4.0 mm
Connection Interface	Two-piece (with titanium alloy screw)	Two-piece (with titanium alloy screw)
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Healing Cap is used for protecting Octa Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using Abutment Screw.	The Octa Healing Cap is used for protecting Octa Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using Abutment Screw.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the reference device.
   - Indication for use, Design, Diameter, Total Length, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. **Differences**
   - N/A

3. **Discussion**
   - The proposed Healing Cap had been FDA cleared under K123988 with product name of 'Octa Healing Cap', but it is being submitted to change their identifier with modification of product name only. Therefore, the subject device and reference device have common in all the items in the comparison chart. Also, these devices were not tested for fatigue strength as they are not placed into occlusion. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Temporary Cylinder

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K123988
Device Name (Compatible Implant System)	**Temporary Cylinder** For AnyOne Onestage Implant System	**Temporary Abutment** For AnyRidge Octa 1 Implant System	**Temporary Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.0 mm	4.0, 4.5, 5.0 mm	5.0 mm
Total Length	10.0 mm	14.85, 15.85, 16.35, 17.35 mm	10.0 mm
Post Height	7.0 mm	10 mm	7.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Octa, Non-Octa	Octa, Non-Octa	Octa, Non-Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Temporary Cylinder is used in conjunction with Octa Abutment to provide support for provisional restoration. It is connected to the Abutment using Abutment Screw	The Temporary Abutment is used in conjunction with Fixture to provide support for provisional restoration. It is connected to Fixture using the Screw.	The Temporary Cylinder is used in conjunction with Octa Abutment to provide support for provisional restoration. It is connected to the Abutment using the Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed Temporary Cylinder had been FDA cleared under K123988, but it is being submitted to change their identifier with modification of material only. Therefore, the proposed Temporary Cylinder and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

EZ Post Cylinder

	Subject Device	Primary Predicate Device	Reference Device
510(k) No.	K210161	K182448	K123988
Device Name (Compatible Implant System)	**EZ Post Cylinder** For AnyOne Onestage Implant System	**EZ Post Abutment** For AnyRidge Octa 1 Implant System	**EZ Post Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.0 mm	4.0, 5.0, 6.0, 7.0 mm	5.0 mm
Total Length	5.5, 7.0 mm	7.85 - 16.35 mm	5.5, 7.0 mm
Post Height	5.5, 7.0 mm	4.0, 5.5, 7.0 mm	5.5, 7.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Octa, Non-Octa	Octa, Non-Octa	Octa, Non-Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The EZ Post Cylinder is used in conjunction with Octa Abutment to provide support for cement and screw type final prosthesis. It is connected to the Abutment using Abutment Screw.	The EZ Post Abutment is a superstructure which is connected to the Fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The EZ Post Cylinder is used in conjunction with Octa Abutment to provide support for cement and screw type final prosthesis. It is connected to the Abutment using Abutment Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, but has made with same material with predicate device. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.

3. Discussion

- The proposed EZ Post Cylinder had been FDA cleared under K123988, but it is being submitted to change their identifier with modification of material only. Therefore, the proposed EZ Post Cylinder and reference device have common in all the items in the comparison chart except the material. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Gold Cylinder

	Subject Device	Reference Device
510(k) No.	K210161	K123988
Device Name (Compatible Implant System)	**Gold Cylinder** For AnyOne Onestage Implant System	**Gold Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design		
Diameter (Ø)	5.1 mm	5.1 mm
Total Length	12.0 mm	12.0 mm
Post Height	10.0 mm	10.0 mm
Angulation	Straight	Straight
Connection Interface	Octa, Non-Octa	Octa, Non-Octa
Material	Body: Gold Alloy Sleeve: POM	Body: Gold Alloy Sleeve: POM
Surface Treatment	N/A	N/A
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Gold Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with Gold alloy. It is connected to the Abutment using Abutment Screw.	The Gold Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with Gold alloy. It is connected to the Abutment using Abutment Screw.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device.
   - Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation
2. **Differences**
   The subject device has the different characteristic for the followings compared to the reference device.
   - N/A
3. **Discussion**
   - The proposed Gold Cylinder had been FDA cleared under K123988, but it is being submitted to change their identifier only without any modification. Therefore, the proposed Gold Cylinder and reference device have common in all the items in the comparison chart. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

CCM Cylinder

	Subject Device	Reference Device
510(k) No.	K210161	K123988
Device Name (Compatible Implant System)	**CCM Cylinder** For AnyOne Onestage Implant System	**CCM Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design		
Diameter (Ø)	5.1 mm	5.1 mm
Total Length	12.0 mm	12.0 mm
Post Height	10.0 mm	10.0 mm
Angulation	Straight	Straight
Connection Interface	Octa, Non-Octa	Octa, Non-Octa
Material	Body: Co-Cr-Mo alloy Sleeve: POM	Body: Co-Cr-Mo alloy Sleeve: POM
Surface Treatment	N/A	N/A
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The CCM Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with CCM alloy. It is connected to the Abutment using Abutment Screw.	The CCM Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with CCM alloy. It is connected to the Abutment using Abutment Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- N/A

3. Discussion

- The proposed CCM Cylinder had been FDA cleared under K123988, but it is being submitted to change their identifier only without any modification. Therefore, the proposed CCM Cylinder and reference device have common in all the items in the comparison chart. Also, the fatigue testing is not considered since the proposed device is a straight type. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Abutment Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K123988	K123988
Device Name (Compatible Implant System)	**Abutment Screw** For AnyOne Onestage Implant System	**Octa Abutment Screw** For AnyOne Internal Implant System	**Multi-unit Abutment Screw** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	2.5, 2.6 mm	2.5 mm	2.95 mm
Total Length	4.85, 5.5 mm	4.85 mm	11.5, 12.5, 13.5, 14.5, 15.5 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Abutment Screw is used for connecting the Angled Abutment to the Fixture, and Healing Cap, Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, CCM Cylinder to the Octa Abutment.	The Octa Abutment Screw is used for connecting the Healing Cap, Temporary Cylinder, EZ Post Cylinder, Gold Cylinder, CCM Cylinder to the Octa Abutment.	The Multi-unit Abutment Screw is used for connecting Multi-unit Abutment to the fixture.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter & Total Length

  The dimension of subject device is slightly different with reference devices, but the half are same as reference device 1, and the other half are lie within combined range of reference device 1&2. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.

3. Discussion

- Some of the proposed Abutment Screw had been FDA cleared under K123988 with product name of 'Octa Abutment Screw', but it is being submitted to change their identifier with modification of product name only, and to add a new dimension. Therefore, the proposed Abutment Screw and reference device have common in all the items in the comparison chart except the Diameter and Total Length. These size differences are explained not affecting on the substantial equivalence.

  On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Meg-Loc Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4
510(k) No.	K210161	K192614	K150537	K182091	K192614
Device Name (Compatible Implant System)	**Meg-Loc Abutment** For AnyOne Onestage Implant System	**Meg-Loc Abutment** For ExFeel Dental Implant System	**Meg-Rhein Abutment** For MiNi Internal Implant System	**Port Abutment** For TS SA, SS SA, US SA, MS SA Implant	**Meg-Magnet Abutment** For AnyRidge, AnyOne, AnyRidge Octa 1, ExFeel Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.
Design					
Diameter (Ø)	3.89 mm	3.89 mm	3.0, 3.1, 3.4 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm	4.5, 5.0 mm
Total Length	7.45, 7.95, 8.95, 9.95, 10.95, 11.95, 12.95, 13.95 mm	7.45, 7.95, 8.95, 9.95, 10.95, 11.95, 12.95 mm	6.55, 6.95, 7.25, 7.75, 7.95, 8.40, 8.75, 8.90, 8.95, 9.75, 9.90, 9.95, 10.75, 10.90, 10.95, 11.75, 11.90, 11.95, 12.75, 12.90, 13.90 mm	Unknown	5.65, 5.85, 6.15, 6.2, 6.75, 6.8, 6.9, 7.15, 7.2, 7.3, 7.4, 7.75, 8.15, 8.2, 8.3, 8.4, 8.75, 9.15, 9.2, 9.3, 9.4, 9.75, 10.15, 10.2, 10.3, 10.4, 10.75, 11.2, 11.3, 11.4, 11.75 mm
Gingival (Cuff) Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8 mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm	0.2, 0.3, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0 mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm
Post Height	1.5 mm	1.5 mm	1.5, 1.7 mm	Unknown	N/A
Angulation	Up to 20°	Up to 20°	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Stainless Steel (ASTM F899-20)
Surface Treatment	Partial TiN coating	Machined	Machined	Partial TiN coating	Partial TiN coating
Single Use	Yes	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Principle of Operation	The Meg-Loc Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Loc Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Rhein Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Port Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Magnet Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Post Height, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Total Length and Gingival (Cuff) Height

  Almost all the total lengths and cuff height of subject device are same with the reference device 1. The only difference is that slight longer length(13.95mm) and cuff height(6.8mm) is added in the subject device but it is a very slight difference(0.5mm) between the longest length(13.9mm) of reference device2, and all the cuff height of subject device lie within combined range of reference device 1~4. The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

- Surface Treatment

  The subject device is treated with partial Tin Coating in upper part while the reference device 1 is not applicable, but has same surface treatment as reference device 4 and Megagen's FDA cleared reference device 3.

3. Discussion

- Some of the proposed Meg-Loc Abutment had been FDA cleared with K192614, but it is being submitted to change their identifier with modification of surface treatment, compatible implant system(ExFeel Internal→AnyOne Onestage), and to add a new dimension. Therefore, the proposed Meg-Loc Abutment and reference device have common in all the items in the comparison chart except the Total Length, Gingival (Cuff) Height and Surface Treatment. These differences are explained not affecting on the substantial equivalence.

  This abutment can be used to correct divergence up to the angulation stated. The fatigue testing presented in this submission for the Angled Abutment was leveraged for the fatigue testing of this device. The Angled Abutment is considered an acceptable worse case for fatigue testing because it, the Meg-Ball, and the Meg-Loc abutments are all made of the same material, the Angled Abutment has a higher Angulation, and the Angled Abutment presents a higher moment arm than the overdenture type abutments.

  On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Meg-Ball Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K192614	K182091
Device Name (Compatible Implant System)	**Meg-Ball Abutment** For AnyOne Onestage Implant System	**Meg-Ball Abutment** For ExFeel Dental Implant System	**Port Abutment** For TS SA, SS SA, US SA, MS SA Implant
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design			
Head Diameter (Ø)	2.25 mm	2.25 mm	N/A
Head Height (Post Height)	4.15 mm	4.15 mm	Unknown
Diameter (Ø)	3.5 mm	3.5 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm
Total Length	10.1, 10.6, 11.6, 12.6, 13.6, 14.6, 15.6, 16.6 mm	10.1, 10.6, 11.6, 12.6, 13.6, 14.6, 15.6 mm	Unknown
Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm
Angulation	Up to 15°	Up to 15°	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Partial TiN coating
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Meg-Ball Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Ball Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Port Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference devices.
   - Indication for use, Design, Head Diameter, Head Length (Post Height), Diameter, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.
2. **Differences**
   The subject device has the different characteristic for the followings compared to the reference devices.
   - Total Length and Gingival (Cuff) Height
     Almost all the total lengths and cuff height of subject device are same with the reference device 1. The only difference is that slight longer length(16.6mm) and cuff height(6.8mm) is added in the subject device, but the difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments, and all the cuff height of subject device lie within combined range of reference device 1&2.

3. Discussion

- Some of the proposed Meg-Ball Abutment had been FDA cleared with K192614, but it is being submitted to change their identifier with modification of, compatible implant system(ExFeel Internal→AnyOne Onestage), and to add a new dimension. Therefore, the proposed Meg-Ball Abutment and reference device have common in all the items in the comparison chart except the Total Length and Gingival (Cuff) Height. These size differences are explained not affecting on the substantial equivalence.
  This abutment can be used to correct divergence up to the angulation stated. The fatigue testing presented in this submission for the Angled Abutment was leveraged for the fatigue testing of this device. The Angled Abutment is considered an acceptable worse case for fatigue testing because it, the Meg-Ball, and the Meg-Loc abutments are all made of the same material, the Angled Abutment has a higher Angulation, and the Angled Abutment presents a higher moment arm than the overdenture type abutments.
  On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Meg-Magnet Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K210161	K192614	K192614	K182091
Device Name (Compatible Implant System)	**Meg-Magnet Abutment** For AnyOne Onestage Implant System	**Meg-Magnet Abutment** For ExFeel Dental Implant System	**Meg-Loc Abutment** AnyRidge, AnyOne, AnyRidge Octa 1, ExFeel Internal Implant System	**Port Abutment** For TS SA, SS SA, US SA, MS SA Implant
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design				
Diameter (Ø)	4.5, 5.0 mm	4.5, 5.0 mm	3.89 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm
Total Length	6.20, 6.25, 6.75, 7.20, 7.75, 8.20, 8.75, 9.20, 9.75, 10.20, 10.75, 11.20, 11.75, 12.20, 12.75 mm	6.20, 6.75, 7.20, 7.75, 8.20, 8.75, 9.20, 9.75, 10.20, 10.75, 11.20, 11.75 mm	6.85, 7.35, 7.45, 7.95, 8, 8.1, 8.35, 8.5, 8.6, 8.95, 9.35, 9.5, 9.6, 9.95, 10.35, 10.5, 10.6, 10.95, 11.35, 11.5, 11.6, 11.95, 12.35, 12.5, 12.6, 12.95, 13.5, 13.6 mm	Unknown
Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8, 6.8mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Stainless Steel (ASTM F899-20)	Stainless Steel (ASTM F899-20)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Partial TiN coating	Partial TiN coating	Machined	Partial TiN coating
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Meg-Magnet Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Magnet Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Loc Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Port Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Total Length and Gingival (Cuff) Height

Almost all the total lengths and cuff height of subject device are same with the reference device 1. The only difference is that slight longer length (6.25, 12.2, 12.75 mm) and cuff height(6.8mm) is added in the subject device, but all the dimensions lie within combined range of reference device 1&2. The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

3. Discussion

- Some of the proposed Meg-Magnet Abutment had been FDA cleared with K192614, but it is being submitted to change their identifier with modification of, compatible implant system(ExFeel Internal→AnyOne Onestage), and to add a new dimension. Therefore, the proposed Meg-Magnet Abutment and reference device have common in all the items in the comparison chart except the Total Length and Gingival (Cuff) Height. These size differences are explained not affecting on the substantial equivalence. Also, the additional fatigue testing is not considered based on FDA Guidance Document being as proposed abutment is straight type. The subject abutment is intended for straight implantation, and is not received single load, because it used for supporting the overdenture that means load is dispersed to the full denture. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Magnet

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K210161	K192614	K192614
Device Name (Compatible Implant System)	**Magnet** For AnyOne Onestage Implant System	**Metal Housing** AnyRidge Internal Implant System, AnyOne Internal Implant System, AnyRidge Octa 1 Implant System	**Meg-Magnet Abutment** For AnyRidge, AnyOne, AnyRidge Octa 1, ExFeel Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.
Design			
Diameter (Ø)	4.5, 5.0 mm	5.0 mm	4.5, 5.0 mm
Total Length	2.2 mm	4.0 mm	5.65, 5.85, 6.15, 6.2, 6.75, 6.8, 6.9, 7.15, 7.2, 7.3, 7.4, 7.75, 8.15, 8.2, 8.3, 8.4, 8.75, 9.15, 9.2, 9.3, 9.4, 9.75, 10.15, 10.2, 10.3, 10.4, 10.75, 11.2, 11.3, 11.4, 11.75 mm
Material	Stainless Steel (ASTM F899-20)	Ti-6Al-4V ELI (ASTM F136-13)	Stainless Steel (ASTM F899-20)
Surface Treatment	TiN coating	Machined	TiN coating
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Magnet is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to Meg-Magnet Abutment to stabilize the overdenture using its magnetic force.	The Metal housing is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to ball type abutment to stabilize the overdenture.	The Meg-Magnet Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter, Total Length

  The dimension of subject device is slightly different with reference device 1, but it is due to the difference of compatible abutment. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
- Material, Surface Treatment

  The material and surface treatment of subject device is different with reference device 1, but has made with same material and surface treatment with reference device 2.

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3. Discussion

- The proposed Magnet and reference device 1 have common in all the items in the comparison chart except the Diameter, Total Length, Material and Surface Treatment. These differences are not affecting on the substantial equivalence since the variety of the size can be possible to operate more precise treatment to meet each patient's condition and the material and surface treatment same as MegaGen's reference device 2.

  On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

Meg-Rhein Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K210161	K150537	K182091	K192614
Device Name (Compatible Implant System)	**Meg-Rhein Abutment** For AnyOne Onestage Implant System	**Meg-Rhein Abutment** For MiNi Internal Implant System	**Port Abutment** For TS SA, SS SA, US SA, MS SA Implant	**Meg-Magnet Abutment** For AnyRidge, AnyOne, AnyRidge Octa 1, ExFeel Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.
Design				
Head Diameter (Ø)	2.5mm	2.5 mm	Unknown	N/A
Head Height (Post Height)	1.7 mm	1.5, 1.7 mm	Unknown	N/A
Diameter (Ø)	3.5 mm	3.0, 3.1, 3.4 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm	4.5, 5.0mm
Total Length	7.45, 9.15, 11.15, 13.15 mm	6.55, 6.95, 7.25, 7.75, 7.95, 8.40, 8.75, 8.90, 8.95, 9.75, 9.90, 9.95, 10.75, 10.90, 10.95, 11.75, 11.90, 11.95, 12.75, 12.90, 13.90 mm	Unknown	5.65, 5.85, 6.15, 6.2, 6.75, 6.8, 6.9, 7.15, 7.2, 7.3, 7.4, 7.75, 8.15, 8.2, 8.3, 8.4, 8.75, 9.15, 9.2, 9.3, 9.4, 9.75, 10.15 10.2, 10.3, 10.4, 10.75, 11.2, 11.3, 11.4, 11.75 mm
Gingival Height	0.3, 2.0, 4.0, 6.0 mm	0.2, 0.3, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0 mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Stainless Steel (ASTM F899-20)
Surface Treatment	Partial TiN coating	Machined	Partial TiN coating	Partial TiN coating
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Meg-Rhein Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Rhein Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Port Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	The Meg-Magnet Abutment is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Head Diameter, Head Height (Post Height), Gingival (Cuff) Height, Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter and Total Length

  The diameter and total length of subject device is slightly different with reference device 1, but it lies within combined range of reference devices 1~3. The difference in cuff height is acceptable for the subject device as it is intended to be used with a tissue level implant, with a portion of the cuff height built into the implant, whereas the predicate device is intended to be used with a bone level implant which requires a cuff height for all abutments.

- Surface Treatment

  The subject device is treated with partial Tin Coating in upper part while the reference device 1 is not applicable, but has same surface treatment as reference device 2 and Megagen's FDA cleared reference device 3.

3. Discussion

- The proposed Meg-Rhein Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Meg-Rhein Abutment and reference device 1 have common in all the items in the comparison chart except the Diameter, Total Length and Surface Treatment. These differences are explained not affecting on the substantial equivalence. Also, the additional fatigue testing is not considered based on FDA Guidance Document being as proposed abutment is straight type. The subject abutment is intended for straight implantation, and is not received single load, because it used for supporting the overdenture that means load is dispersed to the full denture. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference device.

8. Summary of Non-Clinical Testing

The non-clinical testing data which are submitted, referenced, or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

The biocompatibility evaluation has been performed in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The additional biocompatibility testing is not required on the AnyOne Onestage Implant System since AnyOne Onestage Implant System has same material composition, manufacturing process and patient contacting parts as predicate device, AnyRidge Octa 1 Implant System (K182448), ExFeel Dental Implant System (K052369), AnyOne Internal Implant System (K123988) and Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment (K19614).

Modified Surface Treatment

The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'.

AnyOne Onestage Implant System has same surface treatment and manufacturing process as predicate device, AnyRidge Octa 1 Implant System (K182448) and ExFeel Dental Implant System (K052369) for the surface treatment of S.L.A and Anodizing, and Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment (K19614) for TiN coating.

Pyrogen and Endotoxin Test

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP 39 <85>.

Sterilization validation

Sterilization validating testing has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}). The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 5 years shelf life.

Also, the following guidance documents were referred to:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Performance (Physical Properties) Test

The following bench tests have been performed in accordance with ″ISO 14801″ and ″Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment″ to evaluate the performance of the subject devices and the test results met the pre-set criteria.

- Static compression-strength test
- Fatigue test

9. Summary of Clinical Testing

No clinical studies are submitted.

10. Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the AnyOne Onestage Implant System is substantially equivalent to the predicate device as herein.