August 28, 2021

MegaGen Implant Co., Ltd.
% You Jung Kim
Chief Researcher
DaeGyeong Regulatory Affairs Institute
32, Innovalley-ro
Daegu, Dong-gu 41065
REPUBLIC OF KOREA

Re: K203554
Trade/Device Name: AnyOne External Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 30, 2021
Received: July 30, 2021

Dear You Jung 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)*

K203554

Device Name
AnyOne External Implant System

Indications for Use *(Describe)*

The AnyOne External 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.

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

Date: August 28, 2021

1. Applicant / Submitter

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3. Device

- Trade Name: AnyOne External 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:**
  K122231 - Xpeed AnyRidge Internal Implant System
- **Reference Devices:**
  K052369 - ExFeel Dental Implant System
  K123988 - AnyOne Internal Implant System
  K192347 - ST Internal Implant System
  K053353 - Rescue Dental Implant System
  K182448- AnyRidge Octa 1 Implant System
  K150537 - MiNi Internal Implant System
  K192436 - Healing Abutments and Cover Screws
  K110955 - AnyRidge Internal Implant System
  K081302 - Rescue External Implant System
  K160670 - ET US SS Prosthetic System
  K171142 - Healing Cap Multi-Unit Titanium
  K182091 - Osstem Abutment System
  K192614 - Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment

5. Description

- AnyOne External 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 External 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.
  Dental prosthesis is a superstructure of a dental implant system and connecting elements between the dental implant and the crown. It is made of Ti-6A1-4V 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 External 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	**AnyOne External Fixture**	Description	AnyOne External Fixture is a substructure of a dental implant system made of titanium and have the interface connection for External Hex. 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 Ø 5.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 6.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 6.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm
2. Cover Screw & Healing Abutment	**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-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 5.3, 6.2 mm Ø 4.1 x 5.3, 6.2 mm Ø 5.0 x 5.3, 6.2 mm
		Gingival (Cuff) Heights	1.3 mm
		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-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.0 x 6.8, 7.7, 7.8, 8.7, 8.8, 9.7, 9.8, 10.7, 11.8, 12.7 mm Ø 5.0 x 6.8, 7.7, 7.8, 8.7, 8.8, 9.7, 9.8, 10.7, 11.8, 12.7 mm Ø 6.0 x 6.8, 7.7, 7.8, 8.7, 8.8, 9.7, 9.8, 10.7, 11.8, 12.7 mm Ø 7.0 x 6.8, 7.7, 7.8, 8.7, 8.8, 9.7, 9.8, 10.7, 11.8, 12.7 mm
		Gingival (Cuff) Heights	2.0, 3.0, 4.0, 5.0, 7.0 mm
		Angulation	Straight
	Esthetic Healing Abutment	Description	The Esthetic Healing Abutment is used in conjunction with fixture and helps to form suitable emergence profile during period of gingival healing. It is helpful to maintain more thickness of soft tissue and easy to make soft tissue closure against narrow top.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 6.2, 7.2, 8.2 mm Ø 4.1 x 6.2, 7.2, 8.2 mm Ø 5.0 x 6.2, 7.2, 8.2 mm
		Gingival (Cuff) Heights	2.5, 3.5, 4.5 mm
		Angulation	Straight

3. Fixture Level Prosthesis	**Temporary Abutment**	Description	The Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration. It is connected to the Fixture using Abutment Screw. It has a maximum intra-oral use of 180-days.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.9 x 12.0 mm Ø 4.5 x 12.0 mm Ø 5.5 x 12.0 mm
		Post Heights	10.0 mm
		Gingival (Cuff) Heights	1.3 mm
		Angulation	Straight
	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 Abutment Screw.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.0 x 10.0, 12.0 mm Ø 5.0 x 9.0, 10.0, 11.0, 12.0 mm Ø 6.0 x 9.0, 10.0, 11.0, 12.0 mm
		Post Heights	8.0 mm
		Gingival (Cuff) Heights	1.0, 2.0, 3.0, 4.0 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-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.0 x 9.0, 11.0 mm Ø 5.0 x 9.0, 11.0 mm Ø 6.0 x 9.0, 11.0 mm
		Post Heights	7.0 mm
		Gingival (Cuff) Heights	2.0, 4.0 mm
		Angulation	15°, 25°
	Milling Abutment	Description	The Milling Abutment is used in conjunction with fixture and used for establishing an adequate safety margin from occlusal line by hand milling of the post part. It is connected to the Fixture using Abutment Screw. (Note. Only be for Hand Milling with no CAD/CAM)
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.0 x 11.0, 13.0 mm Ø 5.0 x 10.0, 11.0, 12.0, 13.0 mm Ø 6.0 x 10.0, 11.0, 12.0, 13.0 mm Ø 7.0 x 10.0, 11.0, 12.0, 13.0 mm
		Post Heights	9.0 mm
		Gingival (Cuff) Heights	1.0, 2.0, 3.0, 4.0 mm
		Angulation	Straight
	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. It is connected to the Fixture using Abutment Screw.
		Material	Body: Gold Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 4.0 x 11.0 mm Ø 4.5 x 11.2 mm Ø 5.5 x 11.2 mm
		Post Height	10.0 mm
		Gingival (Cuff) Heights	1.0, 1.2 mm
		Angulation	Straight
	Abutment Screw	Description	The Abutment Screw is used for connecting Fixture to Temporary Abutment, EZ Post Abutment, Angled Abutment, Milling Abutment or Gold Abutment.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.5 x 7.5 mm
4.Abutment Level Prosthesis	**Regular Abutment**	Description	The Regular Abutment is used in conjunction with fixture and used for fabrication of either screw or cement retained prosthetics. It is connected to the Fixture using Regular Abutment Screw.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.5 x 3.0, 4.0, 5.5, 7.0, 8.5 mm Ø 4.8 x 3.0, 3.8, 4.8, 5.8 mm
		Post Heights	1.8 mm

		Gingival (Cuff) Heights	1.2, 2.0, 3.0, 4.0 mm
		Angulation	Straight
	Regular Abutment Screw	Description	The Regular Abutment Screw is used for connecting Fixture to Regular Abutment.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.95 x 8.85, 9.85, 10.85, 11.85 mm Ø 3.5 x 7.9, 9.05, 10.55, 12.05, 13.55 mm
	Multi-unit Abutment	Description	The Multi-unit Abutment is used in conjunction with fixture to fabricate screw-retained prosthesis. It is two-piece type and connected the fixture with Multi-unit Abutment Screw.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 2.0, 3.0, 4.0, 5.0, 6.0 mm
		Post Heights	1.0 mm
		Gingival (Cuff) Heights	1.0, 2.0, 3.0, 4.0, 5.0 mm
		Angulation	Straight
	Multi-unit Angled Abutment	Description	The Multi-unit Angled Abutment is used in conjunction with fixture for fabricating screw-retained prosthesis and correcting the prosthetic angulation of implant. It is two-piece type and connected the fixture with Multi-unit Abutment Screw.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 3.65, 4.65, 5.13, 5.65, 6.13 mm
		Post Heights	2.2 mm
		Gingival (Cuff) Heights	2.0, 3.0, 4.0, 5.0 mm
		Angulation	17°, 30°
	Multi-unit Abutment Screw	Description	The Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.4 x 6.8 mm Ø 2.9 x 6.7, 7.7, 8.7, 9.7, 10.7 mm
	Healing Cap	Description	The Healing Cap is used for protecting Regular Abutment or Multi-unit (Angled) Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using its threaded part or Cylinder Screw. It has a maximum intra-oral use of 180-days.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.9 x 4.2 mm Ø 5.0 x 6.1 mm Ø 6.8 x 4.2 mm
	Temporary Abutment	Description	The Temporary Abutment is used in conjunction with Regular Abutment to provide support for provisional restoration. It is connected to the Abutment using Abutment Screw. It has a maximum intra-oral use of 180-days.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 12.35 mm
		Post Heights	7.5 mm
		Gingival (Cuff) Heights	2.8 mm
		Angulation	Straight
	Temporary Cylinder	Description	The Temporary Cylinder is used in conjunction with Multi-unit (Angled) Abutment to provide support for provisional restoration. It is connected to the Abutment using Cylinder Screw. It has a maximum intra-oral use of 180-days.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 12.0 mm
		Post Heights	8.5 mm
		Gingival (Cuff) Heights	3.0 mm
		Angulation	Straight
	EZ Post Cylinder	Description	The EZ Post Cylinder is used in conjunction with Regular Abutment to provide support for cement and screw type final prosthesis. It is connected to the Abutment using Abutment Screw.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 5.0 x 8.5 mm

		Post Heights	7.7 mm
		Gingival (Cuff) Heights	0.8 mm
		Angulation	Straight
	Gold Cylinder	Description	The Gold Cylinder is used in conjunction with Regular Abutment to provide support for screw type final prosthesis by casting with precious metal alloy. It is connected to the Abutment using Abutment Screw.
		Material	Body: Gold Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 4.8 x 13.0 mm
		Post Heights	10.0 mm
		Gingival (Cuff) Heights	3.0 mm
		Angulation	Straight
	CCM Cylinder	Description	The CCM Cylinder is used in conjunction with Regular Abutment or with Multi-unit (Angled) Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy. It is connected to the Abutment using Abutment Screw or Cylinder Screw.
		Material	Body: Co-Cr-Mo Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 4.8 x 13.0, 15.0 mm
		Post Heights	10.0, 13.0 mm
		Gingival (Cuff) Heights	2.0, 3.0 mm
		Angulation	Straight
	Abutment Screw	Description	The Abutment Screw is used for connecting Regular Abutment to Temporary Abutment, EZ Post Cylinder, Gold Cylinder or CCM Cylinder.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.45 x 4.8 mm
	Cylinder Screw	Description	The Cylinder Screw is used for connecting Multi-unit (Angled) Abutment to Healing Cap, Temporary Cylinder or CCM Cylinder.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.0 x 3.4 mm
5.Overdenture Prosthesis	**Meg-Rhein Abutment**	Description	The Meg-Rhein Abutment is used in conjunction with fixture and used to restore the patient's masticatory function by supporting the prosthesis such as artificial teeth and is intended to fixate and stabilize the removable denture exactly by connecting fixture and Denture. It is connected to the Fixture using its threaded part.
		Material	Ti-6A1-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 3.5 x 7.9, 9.9, 11.9 mm Ø 4.1 x 7.9, 9.9, 11.9 mm Ø 5.0 x 7.9, 9.9, 11.9 mm
		Post Heights	1.7 mm
		Gingival (Cuff) Heights	2.0, 4.0, 6.0 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, and to add new dimensions 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	Cover Screw	CP Ti Grade 3	Cover Screw	Ti-6A1-4V ELI	- Material - New models are added
2	K052369	Healing Abutment	CP Ti Grade 3	Healing Abutment	Ti-6A1-4V ELI	- Material - New models are added
3	K052369	Cement Abutment	CP Ti Grade 3	EZ Post Abutment	Ti-6A1-4V ELI	- Material - Product Name
4	K052369	UCLA Gold Abutment	No change	Gold Abutment	No change	- Product Name
5	K052369	Coping Screw	No change	Abutment Screw	No change	- Product Name
6	K052369	Regular Abutment	CP Ti Grade 3	Regular Abutment	Ti-6A1-4V ELI	- Material
7	K052369	Regular Abutment Screw	CP Ti Grade 3	Regular Abutment Screw	Ti-6A1-4V ELI	- Material
8	K052369	Healing Cap	CP Ti Grade 3	Healing Cap	Ti-6A1-4V ELI	- Product Name - Material - New models are added
	K123988	Octa Healing Cap	Ti-6A1-4V ELI			
9	K052369	Temporary Cylinder	CP Ti Grade 3	Temporary Abutment	Ti-6A1-4V ELI	- Product Name - Material - New models are added
	K123988	Temporary Cylinder	CP Ti Grade 4			
10	K052369	Conical Abutment	CP Ti Grade 3	EZ Post Cylinder	Ti-6A1-4V ELI	- Product Name - Material
	K123988	EZ Post Cylinder	CP Ti Grade 4			
11	K052369	Temporary (Cylinder) Screw	No change	Abutment Screw	No change	- Product Name

[Note. 2] The following device described in this submission also had been FDA cleared with **K123988**, but it is being submitted to change their identifier only without any modification.

No.	Predicate Device		Subject Device	Change
	510(k) No.	Product Name	Product Name	
1	K123988	Gold Cylinder	Gold Cylinder	N/A

6. Indication for use

The AnyOne External 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.

7. Basis for Substantial Equivalence

The AnyOne External 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. Performance test of subject device demonstrated the minor difference in size range did not affect substantial equivalence.

The Indications for Use for the subject devices is identical to the primary predicate, K122231 and the reference device, K123988.

In order to demonstrate the difference in design and size ranges 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'. 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 External Fixture

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K122231	K052369	K123988
Device Name (Compatible Implant System)	**AnyOne External Fixture** For AnyOne External Implant System	**XPEED AnyRidge Internal Fixture** For Xpeed AnyRidge Internal Implant System	**ExFeel External Fixture** For ExFeel Dental Implant System	**AnyOne Internal Fixture** For AnyOne Internal 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 External 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 Xpeed AnyRidge 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 fuilly edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0 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 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 06.0 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) & Total Length	Ø3.9 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø4.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø4.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø5.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø5.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø6.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø6.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm	Ø4.0 x 7.2, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.4 x 7.2, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.9 x 7.2, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.4 x 7.2, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.9 x 7.2, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø6.4 x 7.9, 9.4, 10.9, 12.4, 14.4 mm Ø6.9 x 7.9, 9.4, 10.9, 12.4, 14.4 mm Ø7.4 x 7.9, 9.4, 10.9, 12.4, 14.4 mm Ø7.9 x 7.9, 9.4, 10.9, 12.4, 14.4 mm Ø8.4 x 7.9, 9.4, 10.9, 12.4, 14.4 mm	Ø3.25 x 8.1, 9.6, 11.1, 12.6, 14.6, 17.6 mm Ø3.7 x 8.1, 9.6, 11.1, 12.6, 14.6, 17.6 mm Ø3.95 x 8.1, 9.6 mm Ø4.0 x 11.1, 12.6 14.6, 17.6 mm Ø4.95 x 8.1, 9.6, 11.1, 12.6, 14.6 mm	Ø3.9 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø4.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø4.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø5.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø5.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø6.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø6.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø7.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø7.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø8.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm
Implant-to Abutment Connection	External Hex	Internal Conical Connection, Internal Hex	External Hex	Internal Hex
Material	CP Ti Grade 4 (ASTM F67-13)	CP Ti Grade 4 (ASTM F67-13)	CP Ti Grade 3 (ASTM F67-13)	CP Ti Grade 4 (ASTM F67-13)
Single Use	Yes	Yes	Yes	Yes
Surface Treatment	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted (RBM)	Sand-blasted, Large grit, Acid-etched (SLA)

Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf Life	5 years	5 years	5 years	5 years
Feature	- Submerged Implant - Straight / Tapered body shape - cutting edge with self-tapping - 0.8mm thread pitch	- Submerged Implant - Straight / Tapered body shape - cutting edge with self-tapping - 0.8mm thread pitch	- Submerged Implant - Straight / Tapered body shape - cutting edge with self-tapping - 0.5mm & 0.6mm thread pitch	- Submerged Implant - Straight / Tapered body shape - cutting edge with self-tapping - 0.8~1.55mm 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 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.

Substantial Equivalence Discussion

1. Similarities

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

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

2. Differences

- Diameter & Total Length

  The Diameter and Total Length of subject device is slightly different with predicate device but all the subject combination of diameter and length is within the range of the dimension combination of reference device 2.

- Connection

  The subject device has External Hex connection while the predicate device has Internal Hex connection, but has same connection structure as Megagen's FDA cleared reference device 1.

3. Discussion

The proposed AnyOne External Fixture and predicate device have common in Indication for use, Design, Material, Single Use, Surface Treatment, Sterilization, Shelf Life, Feature and Principle of Operation. The 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.

Cover Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K052369	K192347
Device Name (Compatible Implant System)	**Cover Screw** For AnyOne External Implant System	**Cover Screw** For ExFeel Dental Implant System	**Cover Screw** For ST Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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 ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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)	3.5, 4.1, 5.0 mm	3.5, 4.1, 5.0 mm	3.1, 3.6 mm
Total Length	5.3, 6.2 mm	6.2 mm	5.3, 5.9 mm
Gingival Height	1.3 mm	1.3 mm	0.4 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing, Machined	Anodizing	Anodizing
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 1.

   - Indication for use, Design, Diameter, Gingival Height, 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 1.

   - Total Length

     The length of subject device is slightly different with reference device 1, but one of length(6.2mm) is same as reference device 1, and the other one(5.3mm) is same as reference device 2.

   - Material

     The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 2. Also, the leveraged materials are being used for similar devices and intended uses.

3. **Discussion**

   - Some of proposed Cover Screw had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of the material only, and to add new models. Therefore, the proposed Cover Screw and reference device 1 have common in Indication for use, Design, Diameter, Gingival Height, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Healing Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K052369	K053353
Device Name (Compatible Implant System)	**Healing Abutment** For AnyOne External Implant System	**Healing Abutment** For ExFeel Dental Implant System	**Healing Abutment** For Rescue Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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 Rescue® 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. These implants are intended to be used where smaller implants have failed.
Design			
Diameter (Ø)	4.0, 5.0, 6.0, 7.0 mm	4.0, 5.0, 6.0, 7.0 mm	6.0, 8.0, 10.0 mm
Total Length	6.8, 7.7, 7.8, 8.7, 8.8, 9.7, 9.8, 10.7, 11.8, 12.7 mm	7.7, 8.7, 9.7, 10.7, 12.7 mm	6.3, 7.3, 8.3, 9.3, 10.3, 11.3 mm
Gingival Height	2.0, 3.0, 4.0, 5.0, 7.0 mm	2.0, 3.0, 4.0, 5.0, 7.0 mm	2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Anodizing, Machined	Anodizing, Machined	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 1.

- Indication for use, Design, Diameter, 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 1.

- Total Length

  The length of subject device is slightly different with reference device 1, but the half are same as reference device 1, and the other half are lie within combined range of reference device 1 & 2.

- Material

  The subject device is made of titanium alloy while the reference devices are made entirely of commercially pure titanium, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- Some of proposed Healing Abutment had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of the material only, and to add new models. Therefore, the proposed Healing Abutment and reference device 1 have common in Indication for use, Design, Diameter, Gingival Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Esthetic Healing Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K182448	K150537	K192436
Device Name (Compatible Implant System)	**Esthetic Healing Abutment** For AnyOne External Implant System	**Healing Abutment** For AnyRidge Octa 1 Implant System	**Healing Abutment** For MiNi Internal Implant System	**Healing Abutment** For Healing Abutments and Cover Screws
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Dentium Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.
Design				
Diameter (Ø)	3.5, 4.1, 5.0 mm	3.2, 4.2, 5.2, 6.2 mm	3.2, 3.7 mm	4.8, 6.5 mm
Total Length	6.2, 7.2, 8.2 mm	8.6, 9.6, 10.6, 11.6, 12.6, 13.6, 14.6, 15.6 mm	6.3, 6.8, 7.8, 8.8, 9.8 mm	6.15, 6.30, 7.15, 7.30, 8.15, 8.30, 9.15, 9.30 mm
Gingival Height	2.5, 3.5, 4.5 mm	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 mm	2.3, 2.8, 3.8, 4.8, 5.8 mm	Not Known
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing, Machined	Anodizing	Machined	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Principle of Operation	The Esthetic 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.	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 1.
   - Indication for use, Design, Gingival 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 device 1.
   - Diameter & Total Length
     The dimension of subject device is slightly different with reference device 1 but the dimension of subject device lies within combined range of reference devices.
3. **Discussion**
   - The proposed Esthetic Healing Abutment and reference device 1 have common in Indication for use, Design, Gingival Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Temporary Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K052369	K053353	K150537
Device Name (Compatible Implant System)	**Temporary Abutment** For AnyOne External Implant System	**Temporary Cylinder** For ExFeel Dental Implant System	**UCLA Temporary Abutment** For Rescue Dental Implant System	**Temporary Abutment** For MiNi Internal 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 External 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 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 Rescue® 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. These implants are intended to be used where smaller implants have failed.	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.
Design				
Diameter (Ø)	3.9, 4.5, 4.8, 5.5 mm	4.8 mm	5.5, 6.5 mm	3.0 mm
Total Length	12.0, 12.35 mm	12.35 mm	12.0 mm	13.8, 14.2 mm
Post Height	7.5, 10.0 mm	7.5 mm	10.0 mm	8.5 mm
Gingival (Cuff) Height	1.3, 2.8 mm	2.8 mm	1.3 mm	2.3 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	External Hex, External Non-Hex	External Hex, External Non-Hex	External Hex, External Non-Hex	Internal Hex, Internal Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Temporary Abutment is a superstructure which is connected to the Fixtures or Regular Abutment using the Abutment Screw. It is used to provide support for provisional restoration.	The Temporary Cylinder is a superstructure which is connected to the Abutment using the Screw. It is used to provide support for provisional restoration.	The Temporary Abutment is a superstructure which is connected to the Fixtures using the Screw. It is used to provide support for provisional restoration.	The Temporary Abutment is a superstructure which is connected to the Fixtures using the Screw. It is used to provide support for provisional restoration.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, 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 1.
   - Diameter
     The diameter of subject device is slightly different with reference device 1, but all the diameters of subject device lie within range of reference devices.
   - Total Length, Post Height, Gingival (Cuff) Height
     These dimensions are same as reference device 1 and reference device 2.

- Material

  The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 3. Also, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- Some of proposed Temporary Abutment had been FDA cleared with K052639 and K123988 with product name of 'Temporary Cylinder', but it is being submitted to change their identifier with modification of product name and material, and to add new models. Therefore, the proposed Temporary Abutment and reference device 1 have common in Indication for use, Design, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is a straight type and temporarily used.

EZ Post Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K052369	K192347
Device Name (Compatible Implant System)	**EZ Post Abutment** For AnyOne External Implant System	**Cement Abutment** For ExFeel Dental Implant System	**EZ Post Abutment** For ST Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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 ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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)	4.0, 5.0, 6.0 mm	4.0, 5.0, 6.0 mm	4.6, 5.0, 6.0, 7.0 mm
Total Length	9.0, 10.0, 11.0, 12.0 mm	9.0, 10.0, 11.0, 12.0 mm	7.5, 8.5, 9.0, 9.1, 9.5, 10.0, 10.1, 10.5, 10.6, 11.0, 11.1, 11.5, 11.6, 12.0, 12.1, 12.5, 12.6, 13.0, 13.1, 13.5, 13.6, 14.5 mm
Post Height	8.0 mm	8.0 mm	4.0, 5.5, 7.0 mm
Gingival Height	1.0, 2.0, 3.0, 4.0 mm	1.0, 2.0, 3.0, 4.0 mm	1.0, 2.0, 3.0, 4.0, 5.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	External Hex, External Non-Hex	External Hex, External Non-Hex	Internal Hex, Internal Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
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 Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The Cement 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 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.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, Diameter, Total Length, Post Height, 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 1.
   - Material
     The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 2. Also, the leveraged materials are being used for similar devices and intended uses.
3. **Discussion**
   - The proposed EZ Post Abutment had been FDA cleared under K052639 with product name of 'Cement Abutment', but it is being submitted to change their identifier with modification of product name and material. Therefore, the proposed EZ Post Abutment and reference device 1 have common in Indication for use, Design, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type.

Angled Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K110955	K052369
Device Name (Compatible Implant System)	**Angled Abutment** For AnyOne External Implant System	**Angled Abutment** For AnyRidge Internal Implant System	**Cement 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 External 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 AnyRidge 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 o6.0 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 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)	4.0, 5.0, 6.0 mm	4.0, 5.0, 6.0, 7.0 mm	4.0, 5.0, 6.0 mm
Total Length	9.0, 11.0 mm	11.4, 12.4, 13.4, 14.4 mm	9.0, 10.0, 11.0, 12.0 mm
Post Height	7.0 mm	7.0 mm	8.0 mm
Gingival Height	2.0, 4.0 mm	1.8, 2.8, 3.8, 4.8 mm	1.0, 2.0, 3.0, 4.0 mm
Angulation	15°, 25°	15°, 25°	Straight
Connection Interface	External Hex, External Non-Hex	Internal Hex, Internal Non-Hex	External Hex, External Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V 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 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 Cement 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.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, Diameter, Post Height, Angulation, 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 device 1.
   - Total Length, Gingival Height

     The Total Length of subject device is slightly shorter than reference device 1, but it is due to the connection difference, and all the Lengths of subject device lie within range of reference device 2.

     The Gingival Height of subject device is slightly different with reference device 1, but all the Gingival Heights of subject device lie within combined range of reference devices.

     Also, 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.
   - Connection Interface

     The subject device has External Hex connection while the reference device 1 has Internal Hex connection, but has same connection structure as reference device 2. Also, the multiple predicate & reference devices for External Hex connection are presented in the other component comparison charts.

3. Discussion

- The proposed Angled Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared as with reference device 1. Therefore, the proposed Angled Abutment and reference device 1 have common in Indication for use, Design, Diameter, Post Height, Angulation, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence, but the fatigue test was performed on the subject device & reference device 1 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 reference device 1 and the differences are not affecting the substantial equivalence.

Milling Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K081302	K192347
Device Name (Compatible Implant System)	**Milling Abutment** For AnyOne External Implant System	**Milling Abutment** For Rescue External Implant System	**Milling Abutment** For ST Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 Rescue External 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. These implants are intended to be used where smaller implants have failed.	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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)	4.0, 5.0, 6.0, 7.0 mm	6.0, 7.0 mm	4.0, 5.0, 6.0, 7.0 mm
Total Length	10.0, 11.0, 12.0, 13.0 mm	10.0, 11.0, 12.0, 13.0 mm	12.0, 14.5, 14.6 mm
Post Height	9.0 mm	9.0 mm	9.0, 10.5mm
Gingival Height	1.0, 2.0, 3.0, 4.0 mm	1.0, 2.0, 3.0, 4.0 mm	1.5, 3.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	External Hex, External Non-Hex	External Hex, External Non-Hex	Internal Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Milling 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 Milling 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 Milling 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.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, Total Length, Post Height, 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 1.
   - Diameter
     The diameter of subject device is slightly different with reference device 1, but all the diameters of subject device lie within combined range of reference devices.
   - Material
     The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 2. Also, the multiple predicate & reference devices for titanium alloy are presented in the other component comparison charts.
3. **Discussion**
   - The proposed Milling Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Milling Abutment and reference device 1 have common in Indication for use, Design, Total Length, Post Height, Gingival Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type.

Gold Abutment

	Subject Device	Reference Device
510(k) No.	K203554	K052369
Device Name (Compatible Implant System)	**Gold Abutment** For AnyOne External Implant System	**UCLA Gold Abutment** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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)	4.0, 4.5, 5.5 mm	4.0, 4.5, 5.5 mm
Total Length	11.0, 11.2 mm	11.0, 11.2 mm
Post Height	10.0 mm	10.0 mm
Gingival Height	1.0, 1.2 mm	1.0, 1.2 mm
Angulation	Straight	Straight
Connection Interface	External Hex, External Non-Hex	External Hex, External Non-Hex
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 Abutment is connected to the fixture using the Abutment Screw and used for fabrication of abutment for either screw or cement retained restorations by casting gold alloy.	The UCLA Gold Abutment is connected to the fixture and used for fabrication of abutment for either screw or cement retained restorations by casting gold alloy.

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, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. **Differences**

   - N/A

3. **Discussion**

   - The proposed Gold Abutment had been FDA cleared under K052639 with product name of 'UCLA Gold Abutment', but it is being submitted to change their identifier with modification of product name only. Therefore, the proposed Gold Abutment 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 straight type.

Abutment Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K052369	K052369
Device Name (Compatible Implant System)	**Abutment Screw** For AnyOne External Implant System	**Coping Screw** For ExFeel Dental Implant System	**Temporary (Cylinder) 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 External 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 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 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)	2.45, 2.5 mm	2.5 mm	2.45 mm
Total Length	4.8, 7.5 mm	7.5 mm	4.8 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V 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 Fixture to Abutment or Abutment to Cylinder.	The Coping Screw is used for connecting Fixture to Abutment.	The Temporary (Cylinder) Screw is used for connecting Abutment to Cylinder.

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, Total Length, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. **Differences**

   - N/A

3. **Discussion**

   - The proposed Abutment Screw had been FDA cleared under K052639 with product name of 'Coping Screw' and 'Temporary (Cylinder) Screw', but it is being submitted to change their identifier with modification of product name only. Therefore, the proposed Abutment Screw and reference devices have common in all the items in the comparison chart.

Regular Abutment

	Subject Device	Reference Device
510(k) No.	K203554	K052369
Device Name (Compatible Implant System)	**Regular Abutment** For AnyOne External Implant System	**Regular Abutment** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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)	4.5, 4.8 mm	4.5, 4.8 mm
Total Length	3.0, 3.8, 4.0, 4.8, 5.5, 5.8, 7.0, 8.5 mm	3.0, 3.8, 4.0, 4.8, 5.5, 5.8, 7.0, 8.5 mm
Post Height	1.8 mm	1.8 mm
Gingival Height	1.2, 2.0, 3.0, 4.0 mm	1.2, 2.0, 3.0, 4.0 mm
Angulation	Straight	Straight
Connection Interface	External Hex, External Non-Hex	External Hex, External Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Machined
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Regular Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Regular Abutment Screw for aid in prosthetic rehabilitation.	The Regular Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Regular 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 reference device.

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

2. **Differences**

   - Material

     The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, the leveraged materials are being used for similar devices and intended uses.

3. **Discussion**

   - The proposed Regular Abutment had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of material only. Therefore, the proposed Regular Abutment and reference device have common in all the items 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 straight type.

Regular Abutment Screw

	Subject Device	Reference Device
510(k) No.	K203554	K052369
Device Name (Compatible Implant System)	**Regular Abutment Screw** For AnyOne External Implant System	**Regular Abutment Screw** For ExFeel Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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)	2.95, 3.5 mm	2.95, 3.5 mm
Total Length	7.9, 8.85, 9.05, 9.85, 10.55, 10.85, 11.85, 12.05, 13.55 mm	7.9, 8.85, 9.05, 9.85, 10.55, 10.85, 11.85, 12.05, 13.55 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Machined
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	The Regular Abutment Screw is used for connecting Fixture to Regular Abutment.	The Regular Abutment Screw is used for connecting Fixture to Regular 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, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

- Material

The subject device is made of titanium alloy while the reference device is made entirely of commercially pure titanium, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- The proposed Regular Abutment Screw had been FDA cleared with K052639, but it is being submitted to change their identifier with modification of material only. Therefore, the proposed Regular Abutment Screw and reference device have common in all the items except the material. The material difference is explained not affecting on the substantial equivalence.

Multi-unit Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K052369	K160670	K123988
Device Name (Compatible Implant System)	**Multi-unit Abutment** For AnyOne External Implant System	**Regular Abutment** For ExFeel Dental Implant System	**Esthetic-low Abutment** For ET US SS Prosthetic System	**Multi-unit Abutment** For AnyOne 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 External 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 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.	**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.	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)	4.8 mm	4.5, 4.8 mm	4.8, 5.5 mm	5.0 mm
Total Length	2.0, 3.0, 4.0, 5.0, 6.0 mm	3.0, 3.8, 4.0, 4.8, 5.5, 5.8, 7.0, 8.5 mm	2.1, 2.2, 3.0, 3.1, 4.0, 4.1, 5.0, 5.1 mm	6.2, 7.2, 8.2, 9.2, 10.2 mm
Post Height	1.0 mm	1.8 mm	Not Known	1.8 mm
Gingival Height	1.0, 2.0, 3.0, 4.0, 5.0 mm	1.2, 2.0, 3.0, 4.0 mm	Not Known	1.5, 2.5, 3.5, 4.5, 5.5 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	External Non-Hex	External Hex, External Non-Hex	External Hex	Internal Hex, Internal Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	Titanium (ASTM F67)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Machined	Not Known	Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Multi-unit Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Multi-unit Abutment Screw for aid in prosthetic rehabilitation.	The Regular Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Regular Abutment Screw for aid in prosthetic rehabilitation.	The Esthetic-low Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Esthetic-low Abutment Screw for aid in prosthetic rehabilitation.	The Multi-unit 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 reference device 1.
   - Indication for use, Design, Diameter, 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 1.

- Total Length, Post Height, Gingival Height

  Almost all the lengths of subject device lie within combined range of reference device 1 & 2. The only difference is that slight shorter length(2.0mm) is added in the subject device but it is a very slight difference(0.1mm) between the shortest length(2.1mm) of reference device2.

  The Post Height and Gingival Height are slightly different with reference devices, but 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.

- Material

  The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 3. Also, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- The proposed Multi-unit Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared as with refence device 3. It has a different connection interface, but the reference device 1 and reference device 2 have same structure and characteristics with subject device. Therefore, the proposed Multi-unit Abutment and reference device 1 have common in Indication for use, Design, Diameter, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type.

Multi-unit Angled Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K182448	K052369
Device Name (Compatible Implant System)	**Multi-unit Angled Abutment** For AnyOne External Implant System	**Multi-unit Angled Abutment** For AnyRidge Octa 1 Implant System	**Regular 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 External 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 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	4.8 mm	4.5, 4.8 mm
Total Length	3.65, 4.65, 5.13, 5.65, 6.13 mm	6.8, 7.48, 7.8, 8.48, 8.5, 8.8, 8.98, 9.5, 9.98, 10.5 mm	3.0, 3.8, 4.0, 4.8, 5.5, 5.8, 7.0, 8.5 mm
Post Height	2.2 mm	2.2 mm	1.8 mm
Gingival Height	2.0, 3.0, 4.0, 5.0 mm	2.3, 3.3, 4.3mm	1.2, 2.0, 3.0, 4.0 mm
Angulation	17°, 30°	17°, 30°	Straight
Connection Interface	External Hex, External Non-Hex	Internal Octa, Internal Non-Octa	External Hex, External Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V 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 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.	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.	The Regular Abutment is a pre-manufactured prosthetic component connected to the endosseous dental implant using the Regular 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 reference device 1.
   - Indication for use, Design, Diameter, Post Height, Angulation, 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 device 1.
   - Total Length, Gingival Height

     The Total Length of subject device is slightly shorter than reference device 1, but it is due to the connection difference and all the lengths lie within range of reference device 2. The Gingival Height of subject device is slightly different with reference device 1, , 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.
   - Connection Interface

     The subject device has External Hex connection while the reference device 1 has Internal Hex connection, but has same connection structure as reference device 2. Also, the leveraged materials are being used for similar devices and intended uses.

3. **Discussion**
   - The proposed Multi-unit Angled Abutment is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared as with reference device 1. It has a different connection interface, but the reference device 2 has same structure, intended use and characteristics with subject device. The differences are explained not affecting on the substantial equivalence, but the fatigue test was performed on the subject device & reference device 1 to confirm the substantial equivalence 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 reference device 1 and the differences are not affecting the substantial equivalence.

Multi-unit Abutment Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K123988	K182448
Device Name (Compatible Implant System)	**Multi-unit Abutment Screw** For AnyOne External Implant System	**Multi-unit Abutment Screw** For AnyOne Internal Implant System	**Multi-unit Abutment Screw** For AnyRidge Octa 1 Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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.	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)	2.4, 2.9 mm	2.95 mm	2.1 mm
Total Length	6.7, 6.8, 7.7, 8.7, 9.7, 10.7 mm	11.5, 12.5, 13.5, 14.5, 15.5 mm	7.0 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing, Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	The Multi-unit Abutment Screw is used for connecting Multi-unit Abutment to the fixture.	The Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, 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 1.
   - Diameter
     The Diameter of subject device is slightly different with reference device 1, but and all the diameter lie within combined range of reference devices.
3. **Discussion**
   - The proposed Multi-unit Abutment Screw is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Multi-unit Abutment Screw and reference device 1 have common in Indication for use, Design, Connection Interface, Material, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Healing Cap

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K052369	K123988	K171142
Device Name (Compatible Implant System)	**Healing Cap** For AnyOne External Implant System	**Healing Cap** For ExFeel Dental Implant System	**Octa Healing Cap** For AnyOne Internal Implant System	**Healing Cap Multi-Unit Titanium**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Nobel Biocare USA LLC
Indications for Use Statement	The AnyOne External 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 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.	The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.
Design				
Diameter (Ø)	4.9, 5.0, 6.8 mm	4.8, 5.0 mm	4.0, 5.0, 5.2, 6.0 mm	5.0, 6.0, 6.9 mm
Total Length	4.2, 6.1 mm	4.4, 6.1 mm	3.65, 3.7, 3.75, 6.1 mm	4.1, 5.5 mm
Connection Interface	One-piece (with integrated screw) Two-piece (with titanium alloy screw)	One-piece (with integrated screw)	One-piece (with integrated screw) Two-piece (with titanium alloy screw)	One-piece Healing Cap (with integrated screw)
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined	Not Known
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Sterile (Gamma)
Principle of Operation	The Healing Cap is used for protecting Regular Abutment or Multi-unit (Angled) Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using its threaded part or Cylinder Screw	The Healing Cap is used for protecting Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using its threaded part.	The Octa Healing Cap is used for protecting Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using its threaded part or Cylinder Screw	The Healing Cap Multi-unit Titanium is used for protecting Multi-unit Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using its threaded part.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, 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 1.
   - Diameter, Total Length
     The Diameter and Total Length of subject device is slightly different with reference device 1, but all the dimensions lie within combined range of reference devices.
   - Connection Interface
     The subject device has one-piece and two-piece types both while the reference device 1 has one-piece type only, but the reference device 2 has same connection interface as subject device.
   - Material
     The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 2 & 3. Also, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- One of proposed Healing Cap had been FDA cleared with K052639 and K123988, but it is being submitted to change their identifier with modifications of material and product name, and to add new models. Therefore, the proposed Healing Cap and reference device 1 have common Indication for use, Design, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Temporary Cylinder

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K123988	K182091	K182448
Device Name	**Temporary Cylinder** For AnyOne External Implant System	**Temporary Cylinder** For AnyOne Internal Implant System	**Esthetic-low Temporary Cylinder** For Osstem Abutment System	**Temporary Abutment** For AnyRidge Octa 1 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 External 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.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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)	4.8 mm	3.87, 4.8, 5.8 mm	4.8, 5.5 mm	4.0, 4.5, 5.0 mm
Total Length	12.0 mm	10.0 mm	12 mm	14.85, 15.85, 16.35, 17.35 mm
Post Height	8.5 mm	7.0 mm	Not Known	10 mm
Gingival (Cuff) Height	3.0 mm	3.0 mm	Not Known	2.0, 3.0 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Non-Hex	Octa, Non-Octa	Hex	Internal Octa, Internal Non-Octa
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)	Titanium Gr. 3 (ASTM F67)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Not Known	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Temporary Cylinder is used in conjunction with Multi-unit Abutment or Multi-unit Angled Abutment to provide support for provisional restoration. It is connected to the Abutment using Cylinder Screw	The Temporary Cylinder is used in conjunction with Abutment to provide support for provisional restoration. It is connected to the Abutment using Cylinder Screw	The Esthetic-low Temporary Cylinder is used in conjunction with Multi Abutment, US Multi Angled Abutment or Esthetic-low Abutment to provide support for provisional restoration. It is connected to the Abutment using Cylinder Screw	The Temporary Abutment is used in conjunction with Fixture to provide support for provisional restoration. It is connected to Fixture using the Screw.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device 1.

- Indication for use, Design, Diameter, Gingival (Cuff) Height, Angulation, 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 1.

- Total Length, Post Height
  The Total Length and Post Height of subject device is slightly different with reference device 1 but all the dimensions of subject device lie within combined range of reference devices.
- Connection Interface
  The Connection Interface of subject device is different with reference device 1, but Non-Hex in the subject device and Non-Octa in predicate device are same structure without anti-rotation function which can be connected in any direction.

- Material
  The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 3. Also, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- The proposed Temporary Cylinder is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Temporary Cylinder and reference device 1 have common in Indication for use, Design, Diameter, Angulation, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type and temporarily used.

EZ Post Cylinder

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203554	K052369	K192347
Device Name (Compatible Implant System)	**EZ Post Cylinder** For AnyOne External Implant System	**Conical Abutment** For ExFeel Dental Implant System	**EZ Post Abutment** For ST Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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 ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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	5.0 mm	4.6, 5.0, 6.0, 7.0 mm
Total Length	8.5 mm	8.5 mm	7.5 - 14.5 mm
Post Height	7.7 mm	7.7 mm	4.0, 5.5, 7.0 mm
Gingival (Cuff) Height	0.8 mm	0.8 mm	1.0, 2.0, 3.0, 4.0, 5.0mm
Angulation	Straight	Straight	Straight
Connection Interface	Hex, Non-Hex	Hex, Non-Hex	Internal Hex, Internal Non-Hex
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	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 Regular Abutment to provide support for cement and screw type final prosthesis. It is connected to the Abutment using Abutment Screw.	The Conical Abutment is used in conjunction with Regular 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.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the reference device 1.
   - Indication for use, Design, Diameter, Total Length, Post Height, Gingival (cuff) Height, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation.
2. **Differences**
   - Material

     The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 2. Also, the leveraged materials are being used for similar devices and intended uses.
3. **Discussion**
   - The proposed EZ Post Cylinder had been FDA cleared under K052639 with product name of 'Conical Abutment', but it is being submitted to change their identifier with modification of product name and material. Therefore, the proposed EZ Post Cylinder and reference device 1 have common in Indication for use, Design, Diameter, Total Length, Angulation, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The material difference is explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type.

Gold Cylinder

	Subject Device	Reference Device
510(k) No.	K203554	K123988
Device Name (Compatible Implant System)	**Gold Cylinder** For AnyOne External Implant System	**Gold Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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)	4.8 mm	4.0, 4.8, 5.1, 6.0 mm
Total Length	13.0 mm	12.0, 13.0 mm
Post Height	10.0 mm	10.0 mm
Gingival (Cuff) Heights	3.0 mm	2.0, 3.0 mm
Angulation	Straight	Straight
Connection Interface	Hex, Non-Hex	Octa, Non-Octa Hex, Non-Hex
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 Regular Abutment to provide support for screw type final prosthesis by casting with precious metal alloy (Gold alloy). It is connected to the Abutment using Abutment Screw.	The Gold Cylinder is used in conjunction with Abutment to provide support for screw type final prosthesis by casting with precious metal alloy (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 device.
   - Indication for use, Design, Diameter, Total Length, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. **Differences**
   - N/A

3. **Discussion**
   - The proposed Gold Cylinder had been FDA cleared with 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 straight type.

CCM Cylinder

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K123988	K182448	K123988
Device Name	**CCM Cylinder** For AnyOne External Implant System	**CCM Cylinder** For AnyOne Internal Implant System	**CCM Abutment** For AnyRidge Octa 1 Implant System	**Gold Cylinder** For AnyOne Internal 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 External 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.	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)	4.8 mm	4.0, 5.1, 6.0 mm	3.8 mm	4.0, 4.8, 5.1, 6.0 mm
Total Length	13.0, 15.0 mm	12.0 mm	14.65, 16.15 mm	12.0, 13.0 mm
Post Height	10.0, 13.0 mm	10.0 mm	11.6 mm	10.0 mm
Gingival (Cuff) Heights	2.0, 3.0 mm	2.0 mm	1.0 mm	2.0, 3.0 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Hex, Non-Hex	Octa, Non-Octa	Octa, Non-Octa	Octa, Non-Octa Hex, Non-Hex
Material	Body: Co-Cr-Mo Alloy Sleeve: POM	Body: Co-Cr-Mo Alloy Sleeve: POM	Body: Co-Cr-Mo Alloy Sleeve: POM	Body: Gold Alloy Sleeve: POM
Surface Treatment	N/A	N/A	N/A	N/A
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The CCM Cylinder is used in conjunction with Regular Abutment or Multi-unit (Angled) Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy (CCM alloy). It is connected to the Abutment using Abutment Screw or Cylinder Screw.	The CCM Cylinder is used in conjunction with Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy (CCM alloy). It is connected to the Abutment using the Screw.	The CCM Abutment is used in conjunction with Fixture to provide support for screw type final prosthesis by casting with non-precious metal alloy (CCM alloy). It is connected to the Fixture using the Screw.	The Gold Cylinder is used in conjunction with 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 device 1.
   - Indication for use, Design, Angulation, 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 device 1.
   - Diameter, Total Length, Post Height, Gingival (Cuff) Height
     The diameter, Total length and Gingival (cuff) Height of subject device is slightly different with reference device 1 but all the dimensions of subject device lie within range of reference devices. The subject device has same Post Height as predicate for P.H 10.0mm. The only difference is that slight longer height(13.0mm) is added in the subject

device, but the Total Length of subject device lie within combined range of reference devices. Also, 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.

- Connection Interface

The subject device has Hex / Non-Hex connection while the reference device 1 has Octa / Non-Octa connection. However, the connection difference can be covered by the reference device 3. Also, both feature of Hex and Octa provides anti-rotational feature and multiple predicate & reference devices for Hex / Non-Hex are already presented in the other component comparison charts.

3. Discussion

- The proposed CCM Cylinder is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed CCM Cylinder and reference device 1 have common in Indication for use, Design, Angulation, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

  The differences are explained not affecting on the substantial equivalence. Also, the fatigue testing is not considered since the proposed device is straight type.

Cylinder Screw

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K052369	K053353	K123988
Device Name	**Cylinder Screw** For AnyOne External Implant System	**Cylinder Screw** For ExFeel Dental Implant System	**Cylinder Screw** For Rescue Dental Implant System	**Flat Cylinder Screw** For AnyOne Internal 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 External 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 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 Rescue® 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. These implants are intended to be used where smaller implants have failed.	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)	2.0 mm	2.5 mm	2.9	2.1 mm
Total Length	3.4 mm	4.85 mm	4.2 mm	5.9 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)	CP Ti Grade 3 (ASTM F67-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Cylinder Screw is used for connecting Multi-unit (Angled) Abutment to Healing Cap, Temporary Cylinder or CCM Cylinder.	The Cylinder Screw is used for connecting Abutment to Healing Cap or Cylinder.	The Cylinder Screw is used for connecting Abutment to Healing Cap or Cylinder.	The Flat Cylinder Screw is used for connecting Abutment to Healing Cap or Cylinder.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device 1.

- Indication for use, Design, 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 1.

- Diameter, Total Length

  The Diameter and Total Length of subject device is slightly different with reference devices but 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.

- Material

  The subject device is made of titanium alloy while the reference device 1 is made entirely of commercially pure titanium, but has made with same material with reference device 3. Also, the leveraged materials are being used for similar devices and intended uses.

3. Discussion

- The proposed Cylinder Screw is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Cylinder Screw and reference device 1 have common in Indication for use, Design, Connection Interface, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

Meg-Rhein Abutment

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K203554	K182448	K182091	K192614
Device Name (Compatible Implant System)	**Meg-Rhein Abutment** For AnyOne External Implant System	**Meg-Rhein Abutment** For AnyRidge Octa 1 Implant System	**Port Abutment** For Osstem Abutment System	**Meg-Magnet Abutment** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	OSSTEM IMPLANT Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The AnyOne External 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 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.	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)	2.5 mm	2.5 mm	Not Known	N/A
Head Height (Post Height)	1.7 mm	1.7 mm	Not Known	N/A
Diameter (Ø)	3.5, 4.1, 5.0 mm	2.907, 3.407 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm	4.5, 5.0mm
Total Length	7.9, 9.9, 11.9 mm	8.3, 8.8, 9.8, 10.8, 11.8, 12.8, 13.8 mm	Not Known	5.65 – 11.4 mm
Gingival Height	2.0, 4.0, 6.0 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	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-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Stainless Steel (ASTM F899-09)
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 device 1.

- Indication for use, Design, Head Diameter, Head Height (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 1.

- Diameter, Total Length, Gingival Height

  The Diameter, Total Length and Gingival Height of subject device is slightly different with reference device 1 but all the dimensions of subject device lie within combined range of reference devices.

  Surface Treatment

- Surface Treatment

  The subject device is treated with partial Tin Coating in upper part while the predicate device 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 as with reference device 1. Therefore, the proposed Meg-Rhein Abutment and reference device 1 have common in Indication for use, Design, Head Diameter, Head Height (Post Height), Angulation, Connection Interface, Material, Single Use, Sterilization and Principle of Operation. The 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.

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 External Implant System since AnyOne External Implant System has same material composition, manufacturing process and patient contacting parts as predicate device, XPEED AnyRidge Internal Implant System (K122231) for the Fixture, and ST Internal Implant System (K192347), AnyOne Internal Implant System (K123988), AnyRidge Octa 1 Implant System (K182448) and Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment (K19614) for the Abutment.

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 External Implant System has same surface treatment and manufacturing process as predicate device, XPEED AnyRidge Internal Implant System (K122231) for the surface treatment of S.L.A (Fixture), ST Internal Implant System(K192347) for the Anodizing method (Abutment), and Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment (K19614) for TiN coating (Abutment).

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 External Implant System is substantially equivalent to the predicate device as herein.