October 20, 2021

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

Re: K203808
Trade/Device Name: Multi-unit Abutment, Multi-unit Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 9, 2021
Received: September 22, 2021

Dear You Kim:

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

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

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

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

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

Sincerely,

for Andrew 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)*
K203808

Device Name
Multi-unit Abutment, Multi-unit Angled Abutment

Indications for Use *(Describe)*
The Multi-unit Abutment, Multi-unit Angled Abutment 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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for K203808

Date: October 19, 2021

1. **Applicant / Submitter**

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2. **Submission Correspondent**

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3. **Device**

- Trade Name: Multi-unit Abutment, Multi-unit Angled Abutment
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Endosseous dental implant abutment
- Classification Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3630

4. **Predicate Device**

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

- **Reference Devices:**
  K123988 – AnyOne Internal Implant System
  K192401 - Straumann® Screw-Retained Abutments
  K201621 – Magicore II System
  K141457 – Dentium Implantium® and SuperLine® Abutments
  K110955 - AnyRidge Internal Implant System
  K171142 - Healing Cap Multi-Unit Titanium
  K052369 - ExFeel Dental Implant System

5. Description

The Multi-unit Abutment, Multi-unit Angled Abutment is an abutment of a dental implant system to provide support for prosthetic restorations. It is attached to the implants and intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore patient's chewing function.
The Multi-unit Abutment, Multi-unit Angled Abutment consists of straight & angled abutments and prosthetic components in varying sizes for single & multiple unit screw retained restorations.

The Multi-unit Abutment, Multi-unit Angled Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	Xpeed AnyRidge Internal Implant System	Xpeed AnyRidge Internal Fixture	K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	AnyRidge Octa 1 Implant System	AnyRidge Octa 1 Fixture	K182448	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5

The Multi-unit Abutment, Multi-unit Angled Abutment is consisted of the following devices.

Device		Content	
1. Abutment	**Multi-unit Abutment**	Description	The Multi-unit Abutment is used for fabricating screw-retained prosthesis. There are two types of Multi-unit Abutments, N type and S type, depending on the connection type and prosthetics compatibility. The N type (one-piece type) is screwed directly in to the endosseous dental implant by their lower threaded part, and the S type (two-piece type) is connected the fixture with Multi-unit Abutment Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Total Length)	Ø 4.8 x 8.05, 8.75, 8.94, 9.10, 9.75, 9.80, 9.84, 10.75, 10.80, 10.84, 11.75, 11.80, 11.84, 12.80, 12.84 mm Ø 5.0 x 6.2, 7.2, 8.2, 9.2, 10.2 mm
		Post Heights	1.8, 2.2 mm
		Gingival Heights	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm
		Angulation	Straight
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	Multi-unit Angled Abutment	Description	The Multi-unit Angled Abutment is used for fabricating screw-retained prosthesis and correcting the prosthetic angulation of implant. There are two types of Multi-unit Angled Abutments, N type and S type, depending on the prosthetics compatibility. The N type (two-piece type) is connected the fixture with Multi-unit Abutment Screw, and the S type (two-piece type) is connected the fixture with Abutment Screw or Multi Post Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 3.4, 3.9, 3.94, 4.35, 4.4, 4.9, 4.94, 5.35, 5.4, 5.85, 5.9, 5.94, 6.35, 6.4, 6.85, 6.9, 6.94, 7.35, 7.85, 8.85 mm Ø 5.0 x 4.5, 4.7, 5.5, 5.6, 5.7, 5.8, 6.5, 6.6, 6.7, 6.8, 7.5, 7.6, 7.7,

			7.8, 8.6, 8.8 mm
		Post Heights	2.2, 3.9 mm
		Gingival Heights	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, mm
		Angulation	17°, 29°, 30°
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	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.
		Used with	Multi-unit Abutment (S type) in Xpeed AnyRidge & AnyOne Multi-unit Angled Abutment (N type) in Xpeed AnyRidge & AnyOne & AnyRidge Octa 1
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Total Length)	Ø 2.1 x 7.0 mm Ø 2.2 x 4.4 mm Ø 2.4 x 6.8 mm Ø 2.95 x 10.8, 11.5, 11.8, 12.5, 12.8, 13.5, 13.8, 14.5, 15.5 mm
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	Abutment Screw	Description	The Abutment Screw is used for connecting Multi-unit Angled Abutment to the Fixture.
		Used with	Multi-unit Angled Abutment (S type) in AnyOne
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Total Length)	Ø 2.3 x 7.7 mm
		Compatible Implant System	AnyOne Internal Implant System
	Multi Post Screw	Description	The Multi Post Screw is used for connecting Multi-unit Angled Abutment to the Fixture.
		Used with	Multi-unit Angled Abutment (S type) in Xpeed AnyRidge
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Total Length)	Ø 2.1 x 7.0 mm
		Compatible Implant System	Xpeed AnyRidge Internal Implant System
2. Components	**Healing Cap**	Description	The Healing Cap is used for protecting Multi-unit (Angled) Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing. It is connected to the Abutment using Cylinder Screw.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.9 x 4.20 mm Ø 6.8 x 4.20 mm
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	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.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 4.8 x 12.0 mm
		Post Heights	8.5 mm

		Cuff Heights	3.0 mm
		Angulation	Straight
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	CCM Cylinder	Description	The CCM Cylinder is used in conjunction with Multi-unit (Angled) Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo Alloy). It is connected to the Abutment using Cylinder Screw.
		Material	Body: Co-Cr-Mo Alloy / Sleeve: POM
		Dimension (Diameter & Length)	Ø 4.8 x 13.0, 15.0 mm
		Post Height	10.0, 13.0 mm
		Cuff Heights	2.0, 3.0 mm
		Angulation	Straight
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System
	Cylinder Screw	Description	The Cylinder Screw is used for connecting Multi-unit (Angled) Abutment to Healing Cap, Temporary cylinder or CCM Cylinder.
		Material	Ti-6Al-4V ELI (ASTM F136-13)
		Dimension (Diameter & Length)	Ø 2.0 x 3.4 mm
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System

[Note 1] Some of devices described in this submission, **Multi-unit Abutment** and **Multi-unit Abutment screw** in AnyOne Internal Implant System had been FDA cleared with **K123988**, but it is being submitted to change their identifier without any modifications, and to add a new model.

[Note 2] Some of devices described in this submission, **Multi-unit Abutment, Multi-unit Angled Abutment** and **Multi-unit Abutment screw** in AnyRidge Octa 1 Implant System had been FDA cleared with **K182448**, but it is being submitted to change their identifier with modification of surface treatment (Machined →Anodizing), and to add a new model. The changes are explained not affecting substantial equivalence in the part of 'VII. Substantial Equivalence Comparison'.

6. Indication for use

The Multi-unit Abutment, Multi-unit Angled Abutment 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.

7. Basis for Substantial Equivalence

The Multi-unit Abutment, Multi-unit Angled Abutment is substantially equivalent to the predicate devices in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design. The size range of the subject device slightly differ from the predicate device however it is very minor not affecting substantial equivalence.

The subject device is composed of the abutments and prosthetic components that are used for single & multiple unit screw retained restorations, while the predicate devices is addressed complete dental implant system including various fixtures and abutments.
For this reason, the indication for use statement appear to be different between subject and predicate devices but proposed indication is available to apply to predicate devices as well, since the submission device is a sub-set of devices included in the predicate devices.
Also, the point of those indications is ultimately identical in the way that all of devices in subject & predicate devices are intended to be provided the prosthetic support for dental restorations such as crown, bridges, and overdenture to restore patient's chewing function; and this is minor difference in wording not affecting the substantial equivalence of the subject device.
Therefore, the indication for use of subject device is substantially equivalent to the predicate devices.

The Indications for the subject device are identical except for the portion of K182448's indications that are specific to dental implant bodies, and this submission does not include any dental implant bodies, so the omission of this statement is acceptable.

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

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.

Multi-unit Abutment

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) No.	K203808	K182448	K123988	K192401
Device Name	**Multi-unit Abutment** For Multi-unit Abutment, Multi-unit Angled Abutment	**Multi-unit Abutment** For AnyRidge Octa 1 Implant System	**Multi-unit Abutment** For AnyOne Internal Implant System	**Straumann® Screw-Retained Abutments**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Straumann USA, LLC
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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.	Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.
Design				
Diameter (Ø)	4.8, 5.0 mm	4.8 mm	5.0 mm	3.5, 4.6 mm
Total Length	6.2, 7.2, 8.05, 8.2, 8.75, 8.94, 9.1, 9.2, 9.75, 9.8, 9.84, 10.2, 10.75, 10.8, 10.84, 11.75, 11.8, 11.84, 12.8, 12.84 mm	9.8, 10.8, 11.8, 12.8 mm	6.2, 7.2, 8.2, 9.2, 10.2 mm	Not Known
Post Height	1.8, 2.2 mm	2.2 mm	1.8 mm	Not Known
Gingival Height	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm	1.3, 2.3, 3.3, 4.3 mm	1.5, 2.5, 3.5, 4.5, 5.5 mm	1.5, 2.5, 3.5, 4.5 and 5.5 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex, Internal Conical Connection	Internal Conical Connection	Internal Hex, Internal Non-Hex	CrossFit® (NC and RC) (with conical fitting)
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-7Nb
Surface Treatment	Anodizing	Anodizing, Machined	Anodizing	Anodizing

Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Gamma Irradiation
Restoration Type	Single & Multi	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly connected to the endosseous dental implant using its threaded part for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly connected to the endosseous dental implant using its threaded part for aid in prosthetic rehabilitation.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System	AnyRidge Octa 1 Implant System	AnyOne Internal Implant System	Straumann® Bone Level Implants

Substantial Equivalence Discussion

1. Similarities

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

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

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device & reference device 1.

- Total Length, Gingival Height

  Almost all the lengths of subject device lie within combined range of predicate & reference devices. The only difference is that slight longer length(12.84mm) is added in the subject device but it is a very slight difference(0.04mm) between the longest length(12.8mm) of predicate device. The Gingival Height of subject device is slightly different with predicate device, but it does not cause a matter in substantial equivalence since these size differences are very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

- Some of subject device had been FDA cleared with K123988 and K182448, but this submission is being submitted to change their identifier with modification of surface treatment only for K182448 (Machined→Anodizing), and to add new models in the compatible implant system. Therefore, the proposed Multi-unit Abutment and predicate devices have common in Indication for use, Design, Diameter, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type 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 without angulation.

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

Multi-unit Angled Abutment

	Subject Device	Predicate Device	Reference Device1	Reference Device2	Reference Device3
510(k) No.	K203808	K182448	K192401	K201621	K141457
Device Name	**Multi-unit Angled Abutment** For Multi-unit Abutment, Multi-unit Angled Abutment	**Multi-unit Angled Abutment** For AnyRidge Octa 1 Implant System	**Straumann® Screw-Retained Abutments**	**Magic Multiunit Abutment** For Magicore II System	**Angled Screw Abutment** Dentium Implantium® and SuperLine® Abutments
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Straumann USA, LLC	InnoBioSurg Co., Ltd.	Dentium Co., Ltd.
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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.	Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.	The Magicore II System is intended to replace missing teeth to restore chewing function. The Magicore II System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.
Design					
Diameter (Ø)	4.8, 5.0 mm	4.8 mm	3.5, 4.6 mm	4.8, 5.8 mm	4.5 to 5.5 mm
Length	3.4, 3.9, 3.94, 4.35, 4.4, 4.5, 4.7, 4.9, 4.94, 5.35, 5.4, 5.5, 5.6, 5.7, 5.8, 5.85, 5.9, 5.94, 6.35, 6.4, 6.5, 6.6, 6.7, 6.8, 6.85, 6.9, 6.94, 7.35, 7.5, 7.6, 7.7, 7.8, 7.85, 8.6, 8.8, 8.85 mm	5.35, 6.35, 6.85, 7.35, 7.85, 8.85mm	Not Known	3.9 ~ 8.5 mm	Not Known
Post Height	2.2, 3.9 mm	2.2 mm	Not Known	Not Known	Not Known
Gingival Height	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, mm	2.3, 3.3, 4.3mm	1.5, 2.5, 3.5, 4.5 and 5.5 mm	1.5, 2.5, 3.5, 4.5 mm	1.0 to 1.5 mm
Angulation	17°, 29°, 30°	17°, 30°	17°, 30°	5°, 10°, 20°	15° to 30°

Connection Interface	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	CrossFit® (NC and RC) (with conical fitting)	Internal Hex, Internal Non-Hex	Internal Hex, Internal Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-7Nb	Ti-6Al-4V ELI (ASTM F136-13)	Pure Ti-G4 (ASTM F67)
Surface Treatment	Anodizing	Machined	Anodizing	Machined	Tin Coated
Single Use	Yes	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Gamma Irradiation	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi	Single & Multi	Not Known
Principle of Operation	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System	AnyRidge Octa 1 Implant System	Straumann® Bone Level Implants	Magicore II System	Dentium Implantium and SuperLine

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, Sterilization, Restoration type and Principle of Operation

2. Differences

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

- Diameter

  The subject device has same diameter as predicate device and reference device 2 for diameter 4.8mm. The only difference is that slight larger diameter(5.0mm) is added in the subject device. However, it lies within combined range of predicate & reference devices.

- Length, Post Height,

  Almost all the lengths of subject device lie within combined range of predicate & reference devices. The only difference is that slight shorter length(3.4mm) is added in the subject device but it is a very slight difference.

  The subject device has same post height as predicate device for height 2.2mm. The only difference is that slight longer height(3.9mm) is added in the subject device. However, it does not cause a matter in substantial equivalence since these size differences are very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Gingival Height

  The Gingival Height of subject device is slightly different with predicate device, but all the gingival heights of subject device lie within combined range of predicate & reference devices.

- Angulation

  The subject device has same angulation as predicate device & reference device 1 for angle 17° and 30°. The only difference is that slight smaller angle (29°) is added in the subject device but it lies within range of predicate & reference devices and it is a very slight difference (1°) between the biggest angle (30°) of predicate device.

- Connection Interface

  The subject device has Hex & Octa connection while the predicate device has Octa connection only. However, the connection difference can be covered by the reference devices. Also, both feature of Hex and Octa provides anti-rotational feature.

- Surface Treatment

  The subject device has surface treatment of Anodizing while the predicate device has machined surface, but the multiple predicate & reference devices for Anodizing are presented in the other component comparison charts.

3. Discussion

- Some of subject device had been FDA cleared with K182448, but this submission is being submitted to change their

	identifier with modification of surface treatment only, and to add new models in the compatible implant system. Therefore, the proposed Multi-unit Angled Abutment and predicate device have common in Indication for use, Design, Material, Single Use, Sterilization, Restoration type and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue test was performed on the subject and predicate device to confirm the substantial equivalence. The subject device (Multi-unit Angled Abutment) has been selected as the representative specimen in this submission under the consideration of worst case in accordance with 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The test result supports that the subject device is substantially equivalent to the predicate device and the difference is not affecting the substantial equivalence. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

Multi-unit Abutment Screw

	Subject Device	Predicate Device	Reference Device
510(k) No.	K203808	K182448	K123988
Device Name	**Multi-unit Abutment Screw** For Multi-unit Abutment, Multi-unit Angled Abutment	**Multi-unit Abutment Screw** For AnyRidge Octa 1 Implant System	**Multi-unit Abutment Screw** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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)	2.1, 2.2, 2.4, 2.95 mm	2.1 mm	2.95 mm
Total Length	4.4, 6.8, 7.0, 10.8, 11.5, 11.8, 12.5, 12.8, 13.5, 13.8, 14.5, 15.5 mm	7.0 mm	11.5, 12.5, 13.5, 14.5, 15.5 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment to the fixture.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System	AnyRidge Octa1 Internal Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

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

- 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 predicate device & reference Device.

- Diameter, Total Length

  The Diameter of subject device is slightly different with predicate device but all the diameters of subject device lie within combined range of predicate device & reference devices.

  The length of subject device is slightly different with predicate device but it does not cause a matter in substantial equivalence since the difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Surface Treatment

  The other difference is in surface treatment but the anodizing method is for improving the visibility and multiple predicate/reference devices for anodizing are already presented in the other component comparison charts.

3. Discussion

- Some of subject device had been FDA cleared with K123988 and K182448, but this submission is being submitted to change their identifier without any modifications, and to add new models in the compatible implant system. Therefore, the proposed Multi-unit Abutment Screw and predicate device 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.

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

Abutment Screw

	Subject Device	Predicate Device	Reference Device
510(k) No.	K203808	K182448	K123988
Device Name	**Abutment Screw** For Multi-unit Abutment, Multi-unit Angled Abutment	**Abutment Screw** For AnyRidge Octa 1 Implant System	**Abutment Screw** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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)	2.3 mm	2.2 mm	2.3 mm
Total Length	7.7 mm	7.9 mm	10.1 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Abutment screw is used for is used for connecting Multi-unit Angled Abutment to the fixture.	Abutment screw is used for is used for connecting the Abutment to the fixture.	Abutment screw is used for is used for connecting the Abutment to the fixture.
Compatible Implant System	AnyOne Internal Implant System	AnyRidge Octa1 Internal Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

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

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

2. Differences

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

- Total Length

  The length of subject device is slightly shorter than predicate device but it does not cause a matter in substantial equivalence since the difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

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

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

Multi Post Screw

	Subject Device	Reference Device
510(k) No.	K203808	K110955
Device Name	**Multi Post Screw** For Multi-unit Abutment, Multi-unit Angled Abutment	**Multi Post Screw** For AnyRidge Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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 ø6.0 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)	2.1 mm	2.1 mm
Total Length	7.0 mm	8.0 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Principle of Operation	Multi Post Screw is used for connecting Multi-unit Angled Abutment to the Fixture.	Multi Post Screw is used for connecting the Abutment to the Fixture.
Compatible Implant System	Xpeed AnyRidge Internal Implant System	AnyRidge Internal Implant System

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, 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.

- Total Length

  The length of subject device is slightly shorter than reference device but it does not cause a matter in substantial equivalence since the difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

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

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

Healing Cap

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203808	K123988	K171142
Device Name	**Healing Cap** For Multi-unit Abutment, Multi-unit Angled Abutment	**Healing Cap** For AnyOne Internal Implant System	**Healing Cap Multi-Unit Titanium** For Nobel Biocare Multi Unit Abutments
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Nobel Biocare USA LLC
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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, 6.8 mm	4.0, 5.0, 5.2, 6.0 mm	5.0, 6.0, 6.9 mm
Total Length	4.2 mm	3.65, 3.7, 3.75, 5.0 mm	4.1, 5.5 mm
Connection Interface	Two-piece Healing Cap (with titanium alloy screw)	Two-piece Healing Cap (with titanium alloy screw)	One-piece Healing Cap (with integrated screw)
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Not Known
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Sterile (Gamma)
Principle of Operation	Healing Cap is used for protecting Multi-unit Abutment or Multi-unit Angled Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing.	Healing Cap is used for protecting Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing.	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.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa1 Internal Implant System	AnyOne Internal Implant System	Nobel Biocare Multi Unit Abutments

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, Surface Treatment, Sigle 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 Length of subject device is slightly different with reference device 1 but all the diameters and lengths of subject device lie within combined range of reference device 1 & 2.

3. Discussion

- The proposed Healing Cap is being submitted to add in Megagen's existing prosthetic portfolio which had been FDA cleared. Therefore, the proposed Healing Cap and reference devices have common in Indication for use, Design, Connection Interface, Material, Surface Treatment, Sigle Use, Sterilization and Principle of Operation.

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

Temporary Cylinder

	Subject Device	Predicate Device	Reference Device
510(k) No.	K203808	K182448	K123988
Device Name	**Temporary Cylinder** For Multi-unit Abutment, Multi-unit Angled Abutment	**Temporary Abutment** For AnyRidge Octa 1 Implant System	**Temporary Cylinder** For AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The Multi-unit Abutment, Multi-unit Angled Abutment 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.	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, 4.5, 5.0 mm	3.87, 4.8, 5.8 mm
Total Length	12.0 mm	14.85, 15.85, 16.35, 17.35 mm	10.0, 12.35 mm
Post Height	8.5 mm	10 mm	7.0, 7,5 mm
Gingival (Cuff) Height	3.0 mm	2.0, 3.0 mm	2.8, 3.0 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Non-Hex	Internal Octa, Internal Non-Octa	Internal Octa, Non-Octa Internal Hex, Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	Temporary Cylinder is used in conjunction with Multi-unit (Angled) Abutment (N type) to provide support for provisional restoration.	Temporary Abutment is used in conjunction with Fixture to provide support for provisional restoration.	Temporary Cylinder is used in conjunction with Octa Abutment and Multi-unit (Angled) Abutment (S type) to provide support for provisional restoration.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa1 Internal Implant System	AnyRidge Octa1 Internal Implant System	AnyOne Internal Implant System
Substantial Equivalence Discussion			
1. Similarities The subject device has the same characteristic for the followings compared to the predicate device & reference device.			

- Indication for use, Design, Diameter, Gingival (Cuff) Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation

2. Differences

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

- Total Length, Post Height

  The Total Length and Post Height of subject device is slightly different with predicate device, but all the dimensions of subject device lie within combined range of predicate and reference device.

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 predicate devices have common in Indication for use, Design, Diameter, Gingival (cuff) Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation.

  The dimension is slightly different with predicate device, but it does not cause a matter in substantial equivalence since the size difference is very minor, and the variety of the size and angle can be possible to operate more precise treatment to meet each patient's condition. Also, the fatigue testing is not considered since the proposed device is a straight type and temporarily used.

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

CCM Cylinder

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) No.	K203808	K182448	K123988	K123988
Device Name	**CCM Cylinder** For Multi-unit Abutment, Multi-unit Angled Abutment	**CCM Abutment** For AnyRidge Octa 1 Implant System	**CCM Cylinder** For AnyOne Internal Implant System	**CCM Abutment** 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 Multi-unit Abutment, Multi-unit Angled Abutment 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.	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.	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	3.8 mm	4.0, 5.1, 6.0 mm	4.5 mm
Total Length	13.0, 15.0 mm	14.65, 16.15 mm	12.0 mm	15.7 mm
Post Height	10.0, 13.0 mm	11.6 mm	10.0 mm	12.0 mm
Gingival (Cuff) Heights	2.0, 3.0 mm	1.0 mm	2.0 mm	1.0 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex	Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	Internal Hex, Internal 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: Co-Cr-Mo 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
Restoration Type	Single & Multi	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	CCM Cylinder is used in conjunction with Multi-unit (Angled) Abutment (N & S type) to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo Alloy).	CCM Abutment is used in conjunction with Fixture to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo Alloy).	CCM Cylinder is used in conjunction with Octa Abutment to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo Alloy).	CCM Abutment is used in conjunction with Fixture to provide support for screw type final prosthesis by casting with non-precious metal alloy (Co-Cr-Mo Alloy).
Compatible	Xpeed AnyRidge	AnyRidge Octa1 Internal	AnyOne Internal	AnyOne Internal

Implant System	Internal Implant System AnyOne Internal Implant System AnyRidge Octa1 Internal Implant System	Implant System	Implant System	Implant System

Substantial Equivalence Discussion

1. Similarities

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

- Indication for use, Design, Angulation, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation

2. Differences

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

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

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

  The subject device has same Post Height and Cuff Height as reference device 1 for P.H 10.0mm and G.H 2.0mm. The only difference is that slight longer Post Height(13.0mm) and Cuff Height(3.0mm) are added in the subject device, but the total length of subject device lie within combined range of predicate and reference devices.

- Connection Interface

  The subject device has Hex / Non-Hex connection while the predicate device has Octa / Non-Octa connection. However, the connection difference can be covered by the reference device 2. Also, both feature of Hex and Octa provides anti-rotational feature.

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 predicate & reference device have common in Indication for use, Design, Angulation, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation. The dimension is slightly different with predicate device, 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. Also, the fatigue testing is not considered since the proposed device is straight type.

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

Cylinder Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K203808	K123988	K052369
Device Name	**Cylinder Screw** For Multi-unit Abutment, Multi-unit Angled Abutment	**Flat Cylinder Screw** For AnyOne Internal Implant System	**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 Multi-unit Abutment, Multi-unit Angled Abutment 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.	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 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)	2.0 mm	2.1 mm	2.5 mm
Total Length	3.4 mm	5.9 mm	4.85 mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 3 (ASTM F67-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Cylinder Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to Healing Cap, Temporary cylinder or CCM Cylinder.	Flat Cylinder Screw is used for connecting Abutment to Healing Cap or Cylinder.	Cylinder Screw is used for connecting Abutment to Healing Cap or Cylinder.
Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa1 Internal Implant System	AnyOne Internal Implant System	ExFeel Dental Implant System

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, 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 difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

- The proposed 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 devices have common in Indication for use, Design, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The size difference is explained not affecting on the substantial equivalence. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the reference devices.

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 Multi-unit Abutment, Multi-unit Angled Abutment since these have same material composition, manufacturing process and patient contacting parts as predicate devices, AnyOne Internal Implant System (K123988) and AnyRidge Octa 1 Implant System (K182448).

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.

The Multi-unit Abutment, Multi-unit Angled Abutment have same surface treatment and manufacturing process as predicate devices, AnyOne Internal Implant System(K123988) and AnyRidge Octa 1 Implant System (K182448) for the Anodizing method.

Sterilization validation

The subject device is supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}).

Performance (Physical Properties) Test

The bench tests have been performed in accordance with 'ISO 14801' and the recommendations of '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.

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 Multi-unit Abutment, Multi-unit Angled Abutment is substantially equivalent to the predicate device as herein.