October 9, 2019

MegaGen Implant Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

Re: K182448
Trade/Device Name: AnyRidge Octa 1 Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 26, 2019
Received: September 9, 2019

Dear Priscilla Chung:

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 Srinivas Nandkumar, Ph.D.
Acting Division Director
DHT1B: Division of Dental 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)*
K182448

Device Name
AnyRidge Octa 1 Implant System

Indications for Use *(Describe)*

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.

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

(K182448)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Oct 8, 2019

1. Applicant / Submitter

MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalesong-gun,
Daegu, Republic of Korea
Tel: + 82-53-222-2828

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine CA 92620
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

3. Device

- Trade Name: AnyRidge Octa 1 Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary 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:

K140878 Straumann Bone Level Tapered Implants
K170031 Internal Octa Implant System
K153350 IBS Implant system
K110955 AnyRidge Internal Implant System
K171027 Octa Abutment
K072570 NobelActive Multi Unit Abutment
K123988 AnyOne Internal System
K051636 Healing Cap

5. Description:

The AnyRidge Octa 1 Fixture is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method. The fixture offers two types: Normal Thread Type and Deep Thread Type. As the name indicates the Deep Thread Type has slightly deeper threads than the Normal Thread Type.
The abutments are made of Ti-6AI-4V-ELI (ASTM F136-13) except the CCM Abutment. The CCM Abutment is made of Cobalt Chrome Molybdenum (ASTM F1537-11). Also for the Fuse Abutment, the post is covered with provisional restoration that is made of plastic (POM).

The system offers the following components.

No	Component
1	AnyRidge Octa 1 Fixture Ø 3.60 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 3.70 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 4.00 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 4.10 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 4.40 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 4.80 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 5.00 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm Ø 5.50 x 7.00, 7.70, 9.20, 10.70, 12.20, 14.20, 17.20 mm
2	EZ Post Abutment Ø 4.00 x 7.85, 8.85, 9.35, 9.85, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.85 mm Ø 5.00 x 7.85, 8.85, 9.35, 9.85, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm Ø 6.00 x 9.35, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm Ø 7.00 x 9.35, 10.35, 10.85, 11.35, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm
3	Angled Abutment (15, 25°) Ø 4.00 x 10.85, 11.85, 12.85, 13.85, 14.85 mm Ø 5.00 x 10.85, 11.85, 12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35 mm Ø 6.00 x 12.35, 13.35, 14.35, 15.35, 16.35 mm Ø 7.00 x 12.35, 13.35, 14.35, 15.35, 16.35 mm
4	Milling Abutment(Only be for Hand Milling with no CAD/CAM) Ø 6.00 x 12.85, 13.85, 14.85, 15.85, 16.85 mm

	Ø 8.00 x 14.35, 15.35, 16.35, 17.35, 18.35 mm
5	Octa Abutment Ø 3.80 x 7.85, 8.85, 9.85, 10.85, 11.85 mm Ø 4.80 x 9.35, 10.35, 11.35, 12.35, 13.35 mm Ø 5.80 x 10.85, 11.85, 12.85, 13.85, 14.85 mm
6	Multi-unit Abutment Ø 4.80 x 9.80, 10.80, 11.80, 12.80 mm
7	Multi-unit Angled Abutment (17, 30°) Ø 4.8 x 5.35, 6.35, 6.85, 7.35, 7.85, 8.85mm
8	Meg-Rhein Abutment Ø 2.90 7 x 8.30, 8.80, 9.80, 10.80, 11.80, 12.80, 13.80 mm Ø 3.407 x 8.30, 8.80, 9.80, 10.80, 11.80, 12.80, 13.80 mm
9	CCM Abutment Ø 3.80 x 14.65, 16.15 mm
10	Cover Screw Ø 3.00 x 6.60, 7.10 mm Ø 3.70 x 6.60, 7.10 mm Ø 5.00 x 6.60 mm Ø 6.00 x 6.60 mm
11	Healing Abutment Ø 3.20 x 8.60, 9.60, 10.60, 11.60, 12.60, 13.60, 14.60, 15.60 mm Ø 4.20 x 8.60, 9.60, 10.60, 11.60, 12.60, 13.60, 14.60, 15.60 mm Ø 5.20 x 8.60, 9.60, 10.60, 11.60, 12.60, 13.60, 14.60, 15.60 mm Ø 6.20 x 8.60, 9.60, 10.60, 11.60, 12.60, 13.60, 14.60, 15.60 mm
12	Temporary Abutment Ø 4.00 x 14.85, 15.85 mm Ø 4.50 x 16.35, 17.35 mm Ø 5.00 x 16.35, 17.35 mm
13	Fuse Abutment Ø 5.40 x 12.05, 13.55 mm
14	Abutment Screw Ø 2.20 x 7.90 mm
15	Multi-unit Abutment Screw Ø 2.10 x 7.00 mm

The following abutment models have anodized surface treatment.

▪ EZ Post Abutment, Angled Abutment, Milling Abutment, Octa Abutment, Multi-unit Abutment, Multi-unit Angled Abutment, Cover Screw, Healing Abutment, Temporary Abutment, Fixture Mount.

6. Indication for use:

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.

7. Basis for Substantial Equivalence

AnyRidge Octa 1 Implant System is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design. The size range of the predicate device encompasses the size range of the subject device. There are slight differences in design, however, it is very minor not affecting substantial equivalence. There are some verbiage differences in the indications for use statements but it is a difference in language and the indications for use of the two devices are identical.
We have performed the fatigue test to make sure the difference in design does not raise an issue in safety and effectiveness and the test result of the test supported substantial equivalence.

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

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) Number	K182448	K122231	K140878	K170031
Device Name	AnyRidge Octa 1 Implant Fixture	XPEED AnyRidge Internal Implant System	Straumann Bone Level Tapered Implants	Internal Octa Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Straumann USA, LLC	EBI Inc.
Indications for Use Statement	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 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 fully edentulous individuals. It is used to restore a patients 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.	Straumann dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilatation of endentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restoration used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).	The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arched to support crowns, bridges, or overdentures in edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Appearance				
Material	CP Ti Grade 4	CP Ti Grade 4	CP Ti Grade 4	CP Ti Grade 4
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Diameter(Ø)	3.6, 4.0, 4.4, 4.7, 4.8,	4.0, 4.4, 4.9, 5.4, 5.9,	3.3, 4.1, 4.8mm	4.1, 4.8mm

	5.0, 5.5mm	6.4, 6.9, 7.4, 7.9, 8.4mm		
Length (mm)	7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm	7.7, 7.9, 9.2, 9.4, 10.7, 10.9, 12.2, 12.4, 14.20, 14.4, 17.2mm	8, 10, 12, 14mm	7.2~14.2mm
Surface treatment	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Large grit, Acid-etched (S.L.A)
Implant-to-abutment connection	Octa	Hex	Narrow CrossFit Regular CrossFit	Octa
Feature	- Submerged implant - Tapered body - cutting edge with self tapping - 0.8mm thread pitch	- Submerged implant - Tapered body - No cutting edge with self tapping - 0.8mm thread pitch	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8mm thread pitch	- Submerged implant - Parallel walled body - cutting edge with self-tapping - Thread pitch : unknown
Principle of operation	This product 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.	This product 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.	-	-
Shelf Life	5 Years	5 Years	-	5 Years

Substantial Equivalence Discussion

The subject device has the same material, surface treatment, indication for use, and principle of opeartion as the predicate device.

The differences between the subject device and the predicate device is that the subject device has the diameter 3.6mm and cutting edge. The connection type is also different.

The subject device does not include the diameter larger than 5.5mm so the corresponding indication for use of the predicate device for larger implant was excluded. Other than this difference, the IFU statement is the same as the predicate device.

The cutting edge functions as self-tapping by creating a screw path. This difference is covered by the reference device 1 and 2.

The difference in connection type is covered by the reference device 2.

The 3.6mm implant size is covered by the reference device 1.

Despite these differences, the test result of fatigue test supported that the subject device is substantially equivalent to the predicate device.

EZ Post Abutment

	Subject Device	Predicate Device
510(k) Number	K182448	K110955
Device Name	**EZ Post Abutment** for AnyRidge Octa 1 System	**EZ Post** for AnyRidge Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 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 fully edentulous individuals. It is used to restore a patients 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.
Appearance		
Diameter	4.0, 5.0, 6.0, 7.0mm	4.0, 5.0, 6.0, 7.0mm
Post Height	4, 5.5, 7 mm	5.5, 7mm
Gingival Height	0.8, 1.8, 2.8, 3.8, 4.8mm	1.8, 2.8, 3.8, 4.8mm
Connection Interface	Octa, non-octa	Hex, non-hex
Surface treatment	Anodizing	Anodizing
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.
Substantial Equivalence Discussion		
The subject device has the same intended use, material, surface treatment, and design as the predicate device. The diameter range of the subject device is same as the predicate device, yet the subject device has slightly wider range of post height and gingival height. This wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.		

Milling Abutment

	Subject Device	Predicate Device
510(k) Number	K182448	K110955
Device Name	**Milling Abutment** for AnyRidge Octa 1 System	**Milling Abutment** for AnyRidge Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 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 fully edentulous individuals. It is used to restore a patients 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.
Appearance		
Diameter	6.0, 8.0mm	4.0, 5.0, 6.0, 7.0mm
Post Height	9.0mm	9.2mm
Gingival Height	0.8, 1.8, 2.8, 3.8, 4.8mm	1.6, 2.6, 3.6, 4.6mm
Connection Interface	Octa, non-octa	Hex, non-hex
Surface treatment	Anodizing	Anodizing
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6A1-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

The subject device has the same intended use, material, surface treatment, and design as the predicate device. The size range of the subject device is slightly different from the predicate device. This wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.

Octa Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) Number	K182448	K110955	K171027
Device Name	**Octa Abutment** For AnyRidge Octa 1 System	**Octa Abutment** for AnyRidge Internal System	**Octa Abutment** For Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Dentis Co., Ltd.

Indications for Use Statement	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 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 fully edentulous individuals. It is used to restore a patients 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 Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Appearance			
Diameter	3.8mm	4.8mm	3.5, 4.3mm
Gingival Height	0.8, 1.8, 2.8, 3.8, 4.8mm	1, 2, 3, 4, 5mm	Unknown
Connection Interface	Internal Conical connection	Internal Conical connection	Internal Conical connection
Surface treatment	Color anodization	Color anodization	Machined
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.
Substantial Equivalence Discussion			
The subject device has the same intended use, material, surface treatment, connection interface, and design as the predicate device. The diameter of the subject device is covered by the reference device 2, yet the subject device has slightly wider range of gingival height. This wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor.			

Multi-unit Abutment

	Subject Device	Predicate Device 1	Predicate Device 2
510(k) Number	K182448	K072570	K123988
Device Name	**Multi-unit Abutment** for AnyRidge Octa 1 System	**NobelActive Multi Unit Abutment**	**Multi-unit Abutment** for AnyOne Internal System
Manufacturer	MegaGen Implant Co., Ltd.	NOBEL BIOCARE AB	MegaGen Implant Co., Ltd.
Indications for Use Statement	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.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	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 fully edentulous individuals. It is used to restore a patients 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.
Appearance			
Diameter	4.8mm	4.8mm	5.0mm
Gingival Height	1.3, 2.3, 3.3, 4.3mm	1.5, 2.5, 3.5, 4.5mm	1.8, 2.8, 3.8, 4.8mm
Connection Interface	Internal Conical connection	Internal Conical connection	Hex, non-hex
Surface treatment	Color anodization	Machined	Color anodization
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	Multi-unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Multi-unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Substantial Equivalence Discussion			

The subject device has the same intended use, material, surface treatment, connection interface, and design as the predicate devices.
The diameter of the subject device is the same as the reference device 2, yet the subject device has slightly wider range of gingival height. This wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor.

Meg-Rhein Abutment

	Subject Device	Predicate Device
510(k) Number	K182448	K123988
Device Name	**Meg-Rhein Abutment** for AnyRidge Octa 1 System	**Meg-Rhein Abutment** for AnyOne Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 oclusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Appearance		
Head Diameter	2.5mm	2.5mm
Head Height	1.7mm	1.7mm
Connection Interface	Internal Conical connection	Internal Conical connection
Surface treatment	Machined	Machined
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Principle of operation	Meg-Rhein Abutment is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The Meg-Rhein Abutment is screwed into an endosseous implant in the mandible or maxilla.	Meg-Rhein Abutment is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The Meg-Rhein Abutment is screwed into an endosseous implant in the mandible or maxilla.
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Substantial Equivalence Discussion		
The subject device has the same intended use, size, material, surface treatment, connection interface, and design as the predicate devices.		

CCM Abutment

	Subject Device	Predicate Device	Reference Device
510(k) Number	K182448	K161244	K153350
Device Name	**CCM Abutment** for AnyRidge Octa 1 System	**CCM Abutment** For s-Clean OneQ-SL Narrow Implant System	IBS Implant system
Manufacturer	MegaGen Implant Co., Ltd.	Dentis Co.,Ltd	Innobiosurg Co.,Ltd
Indications for Use Statement	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 s-Clean OneQSL Narrow Implant System (3.0, 3.3mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored Immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	The CCM Abutment System is intended to replace missing teeth to restore chewing function. The CCM Abutment System can be placed in support of single or multipleunit restorations including;cement retained, screw retained, 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.
Appearance			
Diameter	3.8mm	4.0mm	3.5, 4, 4.5, 5, 5.5mm
Length	14.65, 16.15	14.5, 15mm	14, 15, 16, 17mm
Connection Interface	Octa, non-octa	Hex, non-hex	Hex, non-hex
Angulation	0°	0°	0°
Principle of operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis
Material	Cobalt Chrome Molybdenum	Cobalt Chrome Molybdenum	Titanium Alloy Poly Diacetate
Substantial Equivalence Discussion			
The subject device has the same intended use, material, and design as the predicate devices. The size range of the subject device is covered by the reference device 2. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.			

Healing Abutment

	Subject Device	Predicate Device 1	Predicate Device 2
510(k) Number	K182448	K110955	K051636
Device Name	**Healing Abutment** for AnyRidge Octa 1 System	**Healing Abutment** for AnyRidge Internal System	**Healing Cap**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Altatec
Indications for Use Statement	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 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 patients 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.	CAMLOG Healing Caps (Cylindrical, wide body, Bottleneck) displace the gingiva from the space above the CAMLOG implant or bar abutment during the CAMLOG implant or bar abutment during the CAMLOG implant healing time and serve for proper gingiva shaping.
Appearance			
Diameter	3.2, 4.2, 5.2, 6.2mm	4.2, 5.2, 6.2, 7.2, 8.0, 10.0mm	3.3, 3.8, 4.3, 5, 6mm
Gingival Height	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5mm	3.5, 4.5, 5.5, 6.5,7.5mm	2, 4, 6mm
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Connection Interface	Internal Conical connection Internal	Internal Conical connection	Internal Conical connection
Surface treatment	Color Anodization	Machined	Machined
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.	Unknown
Material	Ti-6A1-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Substantial Equivalence Discussion			
The subject device has the same intended use, material, connection interface, and design as the predicate devices. The subject device has slightly wider range of size to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The other difference is in surface treatment but we already presented multiple predicate devices for anodizing in the other component comparison charts.			

Temporary Abutment

	Subject Device	Primary Predicate Device
510(k) Number	K182448	K110955
Device Name	**Temporary Abutment** for AnyRidge Octa 1 System	**Temporary Abutment** for AnyRidge Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 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 patients 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.
Appearance		
Diameter	4.0, 5.0mm	4.0mm
Post Height	10mm	10mm
Gingival Height	2.0, 3.0mm	2.0mm
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Connection Interface	Octa, non-octa	He, non-hex
Surface treatment	Color Anodization	Machined
Angulation	0°	0°
Principle of operation	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Substantial Equivalence Discussion		
The subject device has the same intended use, material, and design as the predicate devices. The subject device has slightly wider range of size to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The other difference is in surface treatment but we already presented multiple predicate devices for anodizing in the other component comparison charts. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.		

Fuse Abutment

	Subject Device	Primary Predicate Device
510(k) Number	K182448	K123988
Device Name	**Fuse Abutment** for AnyRidge Octa 1 System	**Fuse Abutment** for AnyOne Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 patients 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.
Appearance		
Diameter	5.4mm	5.3mm
Post Height	5.5, 7.0mm	5.5, 7.0mm
Gingival Height	4.0mm	4.0mm
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Connection Interface	Octa, non-octa	He, non-hex
Angulation	0°	0°
Principle of operation	Fuse Abutment is used in conjunction with fixture to provide support for provisional restoration.	Fuse Abutment is used in conjunction with fixture to provide support for provisional restoration.
Material	Ti-6A1-4V ELI, POM	Ti-6Al-4V ELI, POM
Substantial Equivalence Discussion		
The subject device has the same intended use, material, and similar design as the predicate devices. The subject device has slightly wider diameter than the predicate device but the difference is very minor. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.		

Angled Abutment

	Subject Device	Primary Predicate Device
510(k) Number	K182448	K110955
Device Name	**Angled Abutment** for AnyRidge Octa 1 System	**Angled Abutment** for AnyRidge Internal System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	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 impalnts are dedicated for the molar region.	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 patients 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.
Appearance		
Diameter	4.0, 5.0, 6.0, 7.0mm	3.85, 4.2, 5.0, 6.0mm
Post Height	7.0mm	7.0mm
Gingival Height	0.8, 1.8, 2.8, 3.8, 4.8mm	1.8, 2.8, 3.8, 4.8mm
Connection Interface	Octa, non-octa	Hex, non-hex
Surface treatment	Machined, Color anodization	Color anodization
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	15°, 25°	15°, 25°
Material	Ti-6A1-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.
Substantial Equivalence Discussion		
The subject device has the same intended use, material, and design as the predicate devices. The subject device has slightly wider range of size to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature. Despite these differences, the test result of fatigue test supported that the subject device is substantially equivalent to the predicate device.		

Multi-unit Angled Abutment

	Subject Device	Primary Predicate Device
510(k) Number	K182448	K072570
Device Name	**Multi-unit Angled Abutment** for AnyRidge Octa 1 System	**Nobel Active Multi Unit Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	Nobel BioCare
Indications for Use Statement	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 impalnts are dedicated for the molar region.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Appearance		
Diameter	4.8mm	4.8mm
Gingival Height	2.3, 3.3, 4.3mm	1.5, 2.5, 3.5, 4.5mm
Connection Interface	Octa, non-octa	Hex
Surface treatment	Machined	Machined
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	17°, 30°	17°, 30°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	Multi-unit Angled Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Substantial Equivalence Discussion		
The subject device has the same intended use, material, and design as the predicate devices. The subject device has slightly wider range of size to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The connection interface is also different but both features of Octa and Hex provides anti-rotational feature.		

8. Non-Clinical Testing

- 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 year shelf life.
- The following tests were done to evaluate the fixtures that have SLA treatment: Surface Morphology by energy dispersive spectrometer (EDS), Surface Roughness Analysis, GC(Gas Chromatography)/LC (Liquid chromatography) Analysis, and IC Analysis.
- The fatigue tests were performed on the subject devices in accordance with ISO 14801. The worst case scenarios were chosen based on the FDA guidance “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". The fatigue testing demonstrates that the results of the subject devices are substantially equivalent to the predicate device.
- The fixture has the same material as the predicate device (k122231), and the abutments including the Fuse Abutment have the same material as the predicate device (k123988). The CCM Abutment also has the same material as the predicate device (k123988) made by our company. The biocompatibility of the predicate final products was evaluated under the previous 510K submissions.
- The endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL which was referenced from the USP 39 <85>.

9. Conclusion

Based on the similarities, we conclude that the AnyRidge Octa 1 Implant System is substantially equivalent to the predicate devices.