7/18/2023

MegaGen Implant Co., Ltd.
Eun Park
Assistant Research Engineer
45, Secheon-ro, 7-gil
Daegu, Dasa-eup, Dalesong-gun 42921
Korea, South

Re: K223339
Trade/Device Name: Bone Chamber Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: June 9, 2023
Received: June 16, 2023

Dear Eun Park:

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,

Sherrill Lathrop Blitzer

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223339

Device Name
Bone Chamber Implant

Indications for Use *(Describe)*

● Smaller Implant (Widest Thread Diameter: Ø4.0mm ~Ø5.0mm)

The smaller Implant 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 Implant (Widest Thread Diameter: Ø5.6mm ~Ø7.0mm)

The larger Implant is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:

- Delayed loading

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary for K223339

Date: July 12, 2023

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

Eun Mi Park
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
Daegu, Republic of Korea
Tel: +82-53-222-3859 Fax: +82-53-247-2254
Email: ra4@imegagen.com

3. Device

- Trade Name: Bone Chamber Implant
- Common Name: Implant, Endosseous, Root-Form
- Classification Name: Endosseous Dental Implant
- Classification Product Code: DZE
- Classification regulation: Class II, 21 CFR 872.3640

4. Predicate Device

- **Section I : Smaller Implant**
  Primary Predicate Device: K182448- AnyRidge Octa 1 Implant System
  Reference Device: K122231- XPEED AnyRidge Internal System
  K202832-Implacil Implant System

- **Section II : Larger Implant**
  Primary Predicate Device: K063216- Rescue Internal Implant System
  Reference Devices: K122231- XPEED AnyRidge Internal System
  K182448-AnyRidge Octa 1 Implant System
  K202832-Implacil Implant System

5. Description

- Bone Chamber Implant is a dental implant made of CP Ti Grade 4 with the surface treated by SLA method. It is intended to be surgically placed in the maxillary or mandibular molar arches for smaller implants and in the maxillary or mandibular molar areas for larger implants. The fixture offers two connection types: 2.8 and 3.3 diameter. Also Bone Chamber Implant is characterized by having a chamber on the external surface.

The Bone Chamber Implant is consisted of the following.

Device		**Content**	
1. Fixture Products	**Bone Chamber Implant**	Description	The Bone Chamber Implant is intended to be surgically placed in the maxillary or mandibular molar arches for smaller implants and in the maxillary or mandibular molar areas for larger implants. It purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
		Material	CP Ti Grade 4 of ASTM F67
		Wide Thread Dimension (Diameter & Total Length)	Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø5.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø5.6 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø6.5 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø7.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm

The Bone Chamber Implant is compatible with following MEGAGEN abutments cleared under:

Device	**Fixture – Abutment Connection Diameter (mm)**	**Prosthesis**	**510(k) Number**
Bone Chamber Implant	2.8, 3.3	EZ Post Abutment	K182448
		Angled Abutment	
		Milling Abutment	
		Octa Abutment	
		Multi-unit Abutment	
		Multi-unit Angled Abutment	
		CCM Abutment	
		Octa Abutment	
		Healing Abutment	
		Temporary Abutment	
		Fuse Abutment	
		Abutment Screw	
		Meg-Ball Abutment	K192614
		Meg-Loc Abutment	
		Meg-Magnet Abutment	

6. Indication for use

- Smaller Implant (Wide Thread Diameter: Ø 4.0 ~ Ø 5.0 mm)
  The smaller Implant 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 Implant (Wide Thread Diameter: Ø 5.6 ~ Ø 7.0 mm)
  The larger Implant is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed.
  It is used to restore a patient's chewing function in the following situations and with the clinical protocols:
  -Delayed loading.

7. Basis for Substantial Equivalence

The Bone Chamber Implant is substantially equivalent to the predicate devices in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design. Performance test of subject device demonstrated the minor differences in technological characteristics do not affect substantial equivalence.

The Indications for Use for the subject devices is divided into two types. One is for smaller implant (Wide Thread Diameter: Ø 4.0 ~ Ø 5.0 mm), and the other is for larger implants (Wide Thread Diameter: Ø 5.6 ~ Ø 7.0 mm). The Indication for Use of smaller implants is identical to the primary predicate, K182448. The Indications for Use for the larger implants is similar to the primary predicate device, K063216.
The subject device, compared to the predicate, includes specific information on when the device should be loaded. This aspect does not affect substantial equivalence as the Indications for the subject device fall within the Indications of the predicate device

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'. The test result supports the substantial equivalence to the predicate devices.

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

Bone Chamber Implant

Table 1. Comparison on AnyRidge Octa 1 Implant System (K182448)

	Subject Device	Primary Predicate Device	Reference Device	
510(k) No.	K223339	K182448	K122231	K202832
Device Name	Bone Chamber Implant	AnyRidge Octa 1 Implant System	XPEED AnyRidge Internal Implant System	Implacil Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Implacil De Bortoli Material Odontologico Ltda
Indications for Use Statement	The smaller Implant 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.	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 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	Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit and/or multi-unit restorations. When a one-stage surgical approach is applied, the Implacil Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design				
Widest Thread Diameter (Ø, mm) & Total Length(mm)	· Normal thread Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø5.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm	· Normal thread Ø3.6 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.7 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm · Deep thread Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.8 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.5 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm	· Normal thread Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 · Deep thread Ø6.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø6.9 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø7.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø7.9 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø8.4 X 7.9, 9.4, 10.9, 12.4, 14.4	Ø3.5 X 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm Ø4.0 X.7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm Ø5.0 X 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm
Implant-to Abutment Connection	Internal Octa	Internal Octa	Internal Hex	Internal Hex External Hex
Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Single Use	Yes	Yes	Yes	Yes
Surface Treatment	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Large grit, Acid-etched (SLA)	-
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	-
Shelf Life	5 years	5 years	5 years	-
Feature	- Straight / Tapered body shape - Submerged implant	- Straight / Tapered body shape - Submerged implant - cutting edge with self-tapping	- Submerged implant - Tapered body - cutting edge with self-tapping	-
Chamber	- Yes - Position : Thread	No	No	- Yes - Position : External Surface

	- Angle : 40~60° - Shape : Hemispherical shape			- Angle : 55° - Shape : Radial channel
Principle of Operation	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	-

Substantial Equivalence Discussion

- **Similarities**

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

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

- **Differences**

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

- Design presence of chambers

The presence of chambers of subject device is different with predicate device, but the reference has it, but with different technical characteristics. These differences are explained not affecting on the substantial equivalence.

Subject Device			Predicate			
Model name	**Widest Thread Diameter (Ø,mm)**	**Total Length (mm)**	**Model name**	**Widest Thread Diameter (Ø,mm)**	**Total Length (mm)**	**510k**
BC3308	4.0	7.7	ARO3708	4.0	7.7	K182448
BC3310	4.0	9.2	ARO3710	4.0	9.2	K182448
BC3311	4.0	10.7	ARO3711	4.0	10.7	K182448
BC3313	4.0	12.2	ARO3713	4.0	12.2	K182448
BC3315	4.0	14.2	ARO3715	4.0	14.2	K182448
BC3808	4.4	7.7	ARO4108	4.4	7.7	K182448
BC3810	4.4	9.2	ARO4110	4.4	9.2	K182448
BC3811	4.4	10.7	ARO4111	4.4	10.7	K182448
BC3813	4.4	12.2	ARO4113	4.4	12.2	K182448
BC3815	4.4	14.2	ARO4115	4.4	14.2	K182448
BC4308	5.0	7.7	ARO4808	5.0	7.7	K182448
BC4310	5.0	9.2	ARO4810	5.0	9.2	K182448
BC4311	5.0	10.7	ARO4811	5.0	10.7	K182448
BC4313	5.0	12.2	ARO4813	5.0	12.2	K182448
BC4315	5.0	14.2	ARO4815	5.0	14.2	K182448

- Feature : Cutting edge

Cutting edge is for self-tapping, which does not affect the physical or performance.

- **Discussion**

The proposed Bone Chamber Implant have common in all the terms in the comparison chart except the design presence of chambers and cutting edge. These differences are explained not affecting on the substantial equivalence. The fatigue test was performed on worst case to confirm the substantial equivalence according to “ISO 14801” and “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment”.

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

Table 2. Comparison on Rescue Internal Implant System (K063216)

	Subject Device	Primary Predicate Device	Reference Device		
510(k) No.	K223339	K063216	K122231	K182448	K202832
Device Name (Compatible Implant System)	Bone Chamber Implant	Rescue Internal Implant System	XPEED AnyRidge Internal Implant System	AnyRidge Octa 1 Implant System	Implacil Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Implacil De Bortoli Material Odontologico Ltda
Indications for Use Statement	The larger Implant is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading.	Rescue Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed.	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 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 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.	Implacil Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit and/or multi-unit restorations. When a one-stage surgical approach is applied, the Implacil Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design					
Widest Thread Diameter (Ø, mm) & Total Length(mm)	· Deep thread Ø5.6 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø6.5 X 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø7.0 X 7.7, 9.2, 10.7, 12.2, 14.2 mm	Ø6.0 X 7.0, 8.0, 9.5, 11.0, 12.5 mm Ø6.5 X 7.0, 8.0, 9.5, 11.0, 12.5 mm Ø7.0 X 7.0, 8.0, 9.5, 11.0, 12.5 mm Ø8.0 X 7.0, 8.0, 9.5, 11.0, 12.5 mm	· Normal thread Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 · Deep thread Ø6.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø6.9 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø7.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø7.9 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø8.4 X 7.9, 9.4, 10.9, 12.4, 14.4	· Normal thread Ø3.6 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.7 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm · Deep thread Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø4.8 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø5.5 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm	Ø3.5 X 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm Ø4.0 X.7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm Ø5.0 X 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0 mm
Implant-to Abutment Connection	Internal Octa	Internal Hex	Internal Hex	Internal Octa	Internal Hex External Hex
Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Single Use	Yes	Yes	Yes	Yes	Yes

Surface Treatment	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Acid-etched (RBM)	Sand-blasted, Large grit, Acid-etched (SLA)	Sand-blasted, Large grit, Acid-etched (SLA)	-
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	-
Shelf Life	5 years	5 years	5 years	5 years	-
Feature	- Straight / Tapered body shape - Submerged implant	- Submerged implant - Mose Tapered body - cutting edge with self-tapping	- Submerged implant - Tapered body - cutting edge with self-tapping	- Straight / Tapered body shape - Submerged implant - cutting edge with self-tapping	-
Design – presence of chambers	Yes	No	No	No	Yes
Principle of Operation	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is dental implant which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is dental implant which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	It is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	-

Substantial Equivalence Discussion

- **Similarities**

The subject device has the same characteristic for the followings compared to the predicate device.
Indication for use, Design, Material, Single Use, Sterilization, Shelf Life, Principle of Operation.

- **Differences**

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

- Connection
  The connection of subject device is different with predicate device but has same connection with reference.
- Surface Treatment
  The Surface treatment of subject device is different with predicate device but has same surface treatment with reference.
- Design presence of chambers
  The presence of chambers of subject device is different with predicate device, but the reference has it, but with different technical characteristics. These differences are explained not affecting on the substantial equivalence.
- Feature
  Cutting edge is for self-tapping, which does not affect the physical or performance.
- Widest Thread Diameter & Total Length
  The Widest Thread Diameter and Total Length of subject device are slightly different with predicate device but all the dimensions of subject device lie within the range of predicate device and reference device. But the majority of the Widest Thread diameter and Total length combinations of the subject device is not same to the predicate and reference devices. This difference is to provide a variety of implant dimensions because the deep thread size of the alveolar bone hole varies when a small implant fails. It does not cause a matter in substantial equivalence.

Subject Device			Predicate/ Reference				Difference	
Model name	**Widest Thread Diameter (Ø,mm)**	**Total Length (mm)**	**Model name**	**Widest Thread Diameter (Ø,mm)**	**Total Length (mm)**	**510k**	**Widest Thread Diameter / Length**	**Dimension (mm)**
BC4808	5.6	7.7	ARO4808D	5.5	7.7	K182448	Larger diameter	0.1
BC4810	5.6	9.2	ARO4810D	5.5	9.2	K182448	Larger diameter	0.1
BC4811	5.6	10.7	ARO4811D	5.5	10.7	K182448	Larger diameter	0.1
BC4813	5.6	12.2	ARO4813D	5.5	12.2	K182448	Larger diameter	0.1
BC4815	5.6	14.2	ARO4815D	5.5	14.2	K182448	Larger diameter	0.1
BC5308	6.5	7.7	RSWIR6508	6.5	8	K063216	Shorter length	0.3
BC5310	6.5	9.2	RSWIR6510	6.5	9.5	K063216	Shorter length	0.3
BC5311	6.5	10.7	RSWIR6511	6.5	11	K063216	Shorter length	0.3
BC5313	6.5	12.2	RSWIR6513	6.5	12.5	K063216	Shorter length	0.3
BC5315	6.5	14.2	FALIHX6015	6.9	14.4	K122231	Smaller diameter Shorter length	0.4 0.2
BC5808	7	7.7	RSWIR7008	7	8	K063216	Shorter length	0.3
BC5810	7	9.2	RSWIR7010	7	9.5	K063216	Shorter length	0.3
BC5811	7	10.7	RSWIR7011	7	11	K063216	Shorter length	0.3
BC5813	7	12.2	RSWIR7013	7	12.5	K063216	Shorter length	0.3
BC5815	7	14.2	FALIHX7015	7.4	14.4	K122231	Smaller diameter Shorter length	0.4 0.2

- **Discussion**

The proposed Bone Chamber Implant have common in all the terms in the comparison chart except the connection, surface treatment, design presence of chambers, Cutting edge, Widest Thread Diameter and Total Length. These differences are explained not affecting on the substantial equivalence. The fatigue test was performed on worst case to confirm the substantial equivalence according to “ISO 14801” and “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment”.

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

8. Summary of Non-Clinical Testing

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

Biocompatibility

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

The additional biocompatibility testing is not required on the Bone Chamber Implant since Bone Chamber Implant has same material composition, manufacturing process and patient contacting parts as the previously cleared device, AnyRidge Octa 1 Implant System (K182448) and XPEED AnyRidge Internal System (K122231).

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'.

Bone Chamber Implant has same surface treatment and manufacturing process as the previously cleared device, XPEED AnyRidge Internal System (K122231) for the surface treatment of S.L.A.

Pyrogen and Endotoxin Test

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

Sterilization validation

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

Also, the following guidance documents were referred to:

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

Performance (Physical Properties) Test

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

- Fatigue test

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the metallic MegaGen Dental Implant system as MR Conditional in the MRI environment using scientific rationale and published literature (Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

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 Bone Chamber Implant is substantially equivalent to the predicate device as herein.