January 6, 2023

MegaGen Implant Co., Ltd.
Hyo-Eun Lee
Research Engineer
45, Secheon-ro, 7-gil,
Dasa-eup, Dalseong-gun, Daegu
REPUBLIC OF KOREA

Re: K211812
Trade/Device Name: BLUEDIAMOND IMPLANT, Abutment Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 9, 2022
Received: December 12, 2022

Dear Hyo-Eun Lee:

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211812

Device Name
BLUEDIAMOND IMPLANT, Abutment Screw

Indications for Use *(Describe)*
The BLUEDIAMOND 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.

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 – K211812

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date : January 6, 2023

1. Applicant / Submitter

MegaGen Implant Co., Ltd.
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Daegu, Republic of Korea
Tel: + 82-53-222-2828

2. Submission Correspondent

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3. Device

- Trade Name: BLUEDIAMOND IMPLANT, Abutment Screw
- 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:**

  K063216 - Rescue Internal Implant System

- **Reference Device:**

  K122231 - Xpeed AnyRidge Internal Implant System
  K182448 - AnyRidge Octa 1 Implant System
  K192347 – ST Internal Implant System

5. Description

The BLUEDIAMOND IMPLANT is a substructure of a dental implant system 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 areas. 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 Abutment Screw is used for securing the abutment to the endosseous implant. It is made of Ti-6AL-4V ELI.

The BLUEDIAMOND IMPLANT and Abutment Screw are consisted of the following devices.

No.	Device		Content	
1	Fixture Product	BLUEDIAMOND IMPLANT	Description	The BLUEDIAMOND IMPLANT System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed.
			Material	CP Ti Grade 4 of ASTM F67
			Widest Thread Dimension (Diameter & Total Length)	Ø 5.6 x 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø 6.0 x 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø 6.5 x 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 mm Ø 7.0 x 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 mm
2	Abutment Level Prosthesis	Abutment Screw	Description	Abutment Screw is used for securing the abutment to the endosseous implant.
			Material	Ti-6Al-4V ELI of ASTM F136-13
			Dimension (Diameter & Total Length)	Ø2.20 x 9.9 mm

The BLUEDIAMOND IMPLANT is compatible with following Prosthesis made by our company cleared under;

BLUEDIAMOND IMPLANT			Fixture - Abutment Connection Diameter (mm)	Prosthesis	510(k) Number
FDA-cleared /Subject device	Widest Thread Diameter (mm)	Total Length (mm)			
K182448	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5	7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2	2.8, 3.3	EZ Post Abutment	K182448
				Angled Abutment	
				Milling Abutment	
				Meg-Rhein Abutment	
				Multi-unit Abutment	
				Multi-unit Angled Abutment	
				CCM Abutment	
				Octa Abutment	
Subject device	5.6, 6.0, 6.5, 7.0	7.0, 7.7, 9.2, 10.7, 12.2, 14.2		Healing Abutment	
				Temporary Abutment	
				Fuse Abutment	
				Meg-Ball Abutment	K192614
				Meg-Loc Abutment	
				Meg-Magnet Abutment	

The Abutment Screw, is compatible with following Abutment and implant by our company cleared under;

Abutment Screw			Use for Prosthesis (K182448)	Use for Fixture (K182448 and Subject device)
Model Name	Height(mm)	Connection		
AROAS16B, AROAS16 (K182448)	7.9, 9.9	M1.6	EZ Post Abutment	BLUEDIAMOND IMPLANT
			Angled Abutment	
			Milling Abutment	
			CCM Abutment	
Subject device			Temporary Abutment	
			Fuse Abutment	

6. Indication for use

The BLUEDIAMOND 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.

7. Basis for Substantial Equivalence

The BLUEDIAMOND IMPLANT and Abutment screw are substantially equivalent to the predicate device in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design and size.

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 device.

BLUEDIAMOND IMPLANT

	Subject Device	Predicate Device	Reference Device	
510k	K211812	K063216	K122231	K182448
Device Name (Compatible Implant System)	BLUEDIAMOND IMPLANT	Rescue Internal Implant System	XPEED AnyRidge Internal Implant System	AnyRidge Octa 1 Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
indication for use	The BLUEDIAMOND 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 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 are intended to 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 molar arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in chewing function in the following situations and with the clinical protocols: - Delayed loading - Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.
Design				
Widest Thread Diameter (Ø, mm) & Total Length (mm)	· Normal thread Ø5.6 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 · Deep thread Ø6.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 Ø6.5 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2 Ø7.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2	Ø6.0 X 7.0, 8.0, 9.5, 11.0, 12.5 Ø6.5 X 7.0, 8.0, 9.5, 11.0, 12.5 Ø7.0 X 7.0, 8.0, 9.5, 11.0, 12.5 Ø8.0 X 7.0, 8.0, 9.5, 11.0, 12.5	· 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 Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.7 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 · Deep thread Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.8 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.5 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2
Implant to Abutment Connection	Octa	Hex	Hex	Octa
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)
Surface Treatment	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Acid-etched (RBM)	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf Life	5 Years	5 Years	5 Years	5 Years
Feature	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8 ~ 1.25mm thread pitch	- Submerged implant - Mose Tapered body - cutting edge with self-tapping	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8 ~ 1.55mm thread pitch	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8mm thread pitch

		- 0.8mm thread pitch		
Principle of Operation	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.	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.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device. And the indications for use statement of the subject device has the same intended use as the primary predicate device, K063216, to support prosthetic rehabilitation when used with dental implants in the maxilla or mandible to treat partially or fully edentulous patients.

- Indication for use, Material, Sterilization, Shelf Life, and Principle of Operation.

2. Differences

The subject device has the different characteristic for the following compared to the predicate and reference devices.

- Widest Thread Diameter, Bevel Diameter, Total Length

The Widest Thread Diameter, Bevel diameter and length of subject device is slightly different with predicate device but all the dimensions of subject device lie within combined range of predicate and reference devices. But the majority of the Widest Thread Diameter, Bevel Diameter and length combinations of the subject device are not same to the predicate and reference devices. This difference is to provide a variety of implant dimensions because the size of the alveolar bone hole varies when a small implant fails. It does not affect substantial equivalence.

Subject Device				Predicate/ Reference					Difference		
Model name	Widest Thread Diameter (Ø,mm)	Bevel Diameter (Ø,mm)	Total Length (mm)	Model name	Widest Thread Diameter (Ø,mm)	Bevel Diameter (Ø,mm)	Total Length (mm)	510k	Widest Thread Diameter (Ø,mm)	Bevel Diameter (Ø,mm)	Total Length (mm)
ARO5307	5.6	5.3	7	ARO4807D	5.5	4.8	7	K182448	Larger (0.1)	Larger (0.5)	same
ARO5308	5.6	5.3	7.7	ARO4808D	5.5	4.8	7.7	K182448	Larger (0.1)	Larger (0.5)	Same
ARO5310	5.6	5.3	9.2	ARO4810D	5.5	4.8	9.2	K182448	Larger (0.1)	Larger (0.5)	Same
ARO5311	5.6	5.3	10.7	ARO4811D	5.5	4.8	10.7	K182448	Larger (0.1)	Larger (0.5)	Same
ARO5313	5.6	5.3	12.2	ARO4813D	5.5	4.8	12.2	K182448	Larger (0.1)	Larger (0.5)	Same
ARO5315	5.6	5.3	14.2	FANIHX5515	5.9	4.0	14.2	K122231	Smaller (0.3)	Larger (1.3)	Same
ARO5307D	6	5.3	7	RSWIR6007	6	5.0	7	K063216	Same	Larger (0.3)	Same
ARO5308D	6	5.3	7.7	RSWIR6008	6	5.0	8	K063216	Same	Larger (0.3)	Shorter (0.3)
ARO5310D	6	5.3	9.2	RSWIR6010	6	5.0	9.5	K063216	Same	Larger (0.3)	Shorter (0.3)
ARO5311D	6	5.3	10.7	RSWIR6011	6	5.0	11	K063216	Same	Larger (0.3)	Shorter (0.3)
ARO5313D	6	5.3	12.2	RSWIR6013	6	5.0	12.5	K063216	Same	Larger (0.3)	Shorter (0.3)
ARO5315D	6	5.3	14.2	FALIHX6015	6.4	5.5	14.4	K122231	Smaller (0.4)	Smaller (0.2)	Shorter (0.2)
ARO5807D	6.5	5.3	7	RSWIR6507	6.5	5.5	7	K063216	Same	Smaller (0.2)	Same
ARO5808D	6.5	5.3	7.7	RSWIR6508	6.5	5.5	8	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO5810D	6.5	5.3	9.2	RSWIR6510	6.5	5.5	9.5	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO5811D	6.5	5.3	10.7	RSWIR6511	6.5	5.5	11	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO5813D	6.5	5.3	12.2	RSWIR6513	6.5	5.5	12.5	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO5815D	6.5	5.3	14.2	FALIHX6515	6.9	5.5	14.4	K122231	Smaller (0.4)	Smaller (0.2)	Shorter (0.2)
ARO6307D	7	5.3	7	RSWIR7007	7	5.5	7	K063216	Same	Smaller (0.2)	Same
ARO6308D	7	5.3	7.7	RSWIR7008	7	5.5	8	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO6310D	7	5.3	9.2	RSWIR7010	7	5.5	9.5	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO6311D	7	5.3	10.7	RSWIR7011	7	5.5	11	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO6313D	7	5.3	12.2	RSWIR7013	7	5.5	12.5	K063216	Same	Smaller (0.2)	Shorter (0.3)
ARO6315D	7	5.3	14.2	FALIHX7015	7.4	5.5	14.4	K122231	Smaller (0.4)	Smaller (0.2)	Shorter (0.2)

- Feature

The thread pitch of subject device is slightly different with predicate device but all the thread pitch of subject device lies within range of reference.

- Implant to Abutment Connection

  The connection of subject device is different with predicate device but has same connection as the reference device.

- Surface treatment

The surface treatment of subject device is different with predicate device but has same surface treatment as the reference device.

3. Discussion

The proposed BLUEDIAMOND implant have common in all the terms in the comparison chart except the Widest Thread Diameter, length, feature, implant to abutment connection, and surface treatment. These differences are explained not affecting on the substantial equivalence. And the differences in the indications for use statement between the subject device and primary predicate device, K063216, are only minor changes in wording and do not affect the intended use for demonstrating 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.

Abutment Screw

	Subject Device	Predicate Device	Reference Device	
510k	Not yet	K063216	K182448	K192347
Device Name	Abutment Screw for BLUEDIAMOND IMPLANT System	Rescue Internal Implant System	Abutment Screw for BLUEDIAMOND IMPLANT System	Abutment Screw for ST Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
indication for use	The BLUEDIAMOND 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 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 are intended to be used where smaller implants have failed.	Abutment Screw is used for securing the abutment to the endosseous implant.	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design				
Diameter (Ø, mm)	2.2	3.1	2.2	2.15, 2.35
Total Length (mm)	9.9	7.9	7.9	8.4, 10.2
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined	Machined	Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Abutment Screw is used for connecting Fixture to Abutment or Abutment to Cylinder.	The Abutment Screw is used for connecting Fixture to Abutment or Abutment to Cylinder.	The Abutment Screw is used for connecting Fixture to Abutment or Abutment to Cylinder.	Abutment Screw is used for securing the abutment to the endosseous implant.

Substantial Equivalence Discussion

1. **Similarities**

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

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

2. **Difference**

- Total Length

The Total Length of subject device is slightly different with the prior cleared reference device but all the dimensions of subject device lie within combined range of the prior cleared reference devices.

The subject device compared with the prior cleared reference device(K182448), the length of the part to which the Driver is fastened is increased to aid in fastening by the Hand Driver. Therefore, there is no significant difference in product performance and the difference does not affect substantial equivalence.

3. **Discussion**

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

8. Summary of Non-Clinical Testing

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

Biocompatibility

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

The BLUEDIAMOND IMPLANT and Abutment Screw have the same material composition, manufacturing process and patient contacting parts as the previously cleared devices, XPEED AnyRidge Internal System (K122231) 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 Abutments – Guidance for Industry and FDA Staff".

The BLUEDIAMOND IMPLANT has same surface treatment and manufacturing process as the previously cleared device, AnyRidge Octa 1 Fixture (K182448) for the surface treatment of S.L.A(Fixtures).

The Abutment Screw has same surface treatment and manufacturing process as the previously cleared device, Abutment Screw for ST Internal Implant System(K192347). The purpose of Anodizing for Abutment Screw is to distinguish the connection type of screw body with the naked eyes for convenience. And It doesn't affect device's fundamental functions, safety and effectiveness.

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 and Shelf life

For the Implants (provided sterile), sterilization validation testing has been performed in accordance with ISO 11137 to verify the sterility assurance level (10^{-6}). Validation Testing was conducted per FDA Guidance: "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile." 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.

For the Abutment Screws (provided non-sterile), steam sterilization validation has been performed in accordance with the requirements of ISO 17665-1, ISO 17665-2 and FDA Guidance: "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." Validation Testing was conducted on a worst-case test article from our prior predicate device submission, K220562.

Performance test

This subject device has similar design and same indication for use, principle of operation, technical characteristics and function except for Widest Thread Diameter and Total length. According to the diagram for determining the worst-case conditions of Annex B of ISO 14801, devices that had already been submitted in advance have already been selected as the worst-case scenario. Therefore, the Widest Thread Diameter of subject device is larger compared with the previously cleared device (K182448), it doesn't affect the performance change of the product.

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 BLUEDIAMOND IMPLANT and Abutment Screw are substantially equivalent to the predicate device as here.