December 27, 2024

Megagen Implant Co. Ltd
Hyo-Eun Lee
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K241972
Trade/Device Name: BLUEDIAMOND IMPLANT
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 26, 2024
Received: November 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241972

Device Name

BLUEDIAMOND IMPLANT

Indications for Use *(Describe)*

The BLUEDIAMOND IMPLANT 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 in the following situations and with the clinical protocols:
- Delayed loading
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.

For the BLUEDIAMOND IMPLANTS with a Thread Length of 5mm,
It is indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks.
It is specifically recommended for:
- Fixed partial dentures/splinted units (one implant per unit)
- Pontic cases in combination with at least one longer implant
- Fully edentulous cases with at least one 5 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants

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 BLUEDIAMOND IMPLANT (K241972)

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

Date Prepared: December 26, 2024

1. Applicant / Submitter

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

2. Submission Correspondent

Hyo-Eun, Lee
MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
Daegu, Republic of Korea
Tel: +82-53-222-3860 Fax: +82-53-289-3414
Email: ra7@imegagen.com

3. Device

- Trade Name: BLUEDIAMOND IMPLANT
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Classification Regulation: 872.3640
- Primary Product Code: DZE

4. Predicate Device

- **Primary Predicate Device:**
  K231967 - ARi ExCon Implant System

- **Reference Device:**
  K182448 - BLUEDIAMOND IMPLANT System
  K210852 - Noris Medical Dental Implants System – Cortical
  K230618 - MegaGen Dental Implant Systems Portfolio – MR Conditional
  K202942 - Straumann® 4 mm Short Implants, Straumann USA, LLC
  K213599 - SuperLine, Dentium Co., Ltd.
  K200586 - Straumann® TLX Implant System, Straumann USA, LLC
  K122231 - Xpeed AnyRidge Internal Implant System
  K192614 - Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment
  K210161 - AnyOne Onestage Implant System
  K203808 - Multi-unit Abutment, Multi-unit Angled Abutment
  K233450 - MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment;

Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw

5. Description

- The BLUEDIAMOND IMPLANT is a dental implant body system made of CP Ti Grade 4 with the surface treated by SLA method. It is intended to be placed in the maxillary or mandibular areas to restore masticatory function.
  It has different thread lengths depending on the diameter and length. The Implanted length of the device is the length that is implanted into the bone, including the length from the thread to the shoulder, which is the non-threaded part.
  The Gingival (Cuff) area of the device has grooves; the bottom of the grooves indicate the implantable length.

- The **BLUEDIAMOND IMPLANT** is consisted of the following components.

Device		Content		
BLUEDIAMOND IMPLANT	Cuff Type	Description	The BLUEDIAMOND IMPLANT is a dental implant body system made of CP Ti Grade 4 with the surface treated by SLA method. It is intended to be placed in the maxillary or mandibular areas to restore masticatory function.	
		Material	CP Ti Grade 4 of ASTM F67	
		Dimension (mm)	Diameter X Total Length (Thread Length)	· Normal Thread Ø 4.0 x 9.0, 11.0, 13.0, 15.0 (7.0, 9.0) Ø 4.4 x 7.0, 9.0, 11.0, 13.0, 15.0 (5.0, 7.0, 9.0) Ø 4.7 x 7.0, 9.0, 11.0, 13.0, 15.0 (5.0, 7.0, 9.0) · Deep Thread Ø 4.4 x 9.0, 11.0, 13.0, 15.0 (5.0, 7.0, 9.0) Ø 4.8 x 7.0, 9.0, 11.0, 13.0, 15.0 (5.0, 7.0, 9.0) Ø 5.1 x 7.0, 9.0, 11.0, 13.0, 15.0 (5.0, 7.0, 9.0)
			Implanted Length (Thread to Shoulder Height)	· Normal Thread Ø 4.0: 8.0, 9.0, 10.0, 11.0 (1.0, 2.0) Ø 4.4: 7.0, 8.0, 9.0, 10.0, 11.0 (1.0, 2.0) Ø 4.7: 7.0, 8.0, 9.0, 10.0, 11.0 (1.0, 2.0) · Deep Thread Ø 4.4: 8.0, 9.0, 10.0, 11.0 (1.0, 2.0) Ø 4.8: 7.0, 8.0, 9.0, 10.0, 11.0 (1.0, 2.0) Ø 5.1: 7.0, 8.0, 9.0, 10.0, 11.0 (1.0, 2.0)
			Gingival (Cuff) Height	2.0, 3.0, 4.0

- The BLUEDIAMOND IMPLANTs are compatible to abutments of The BLUEDIAMOND IMPLANT System from K182448, K192614, K210161, K203808, K233450.

6. Indication for use

The BLUEDIAMOND IMPLANT 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 in the following situations and with the clinical protocols:
- Delayed loading
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.

For the BLUEDIAMOND IMPLANTS with a Thread Length of 5mm,
It is indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where

a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks.

It is specifically recommended for:

- Fixed partial dentures/splinted units (one implant per unit)
- Pontic cases in combination with at least one longer implant
- Fully edentulous cases with at least one 5 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants

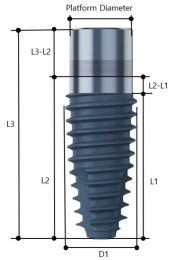
7. Basis for Substantial Equivalence

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

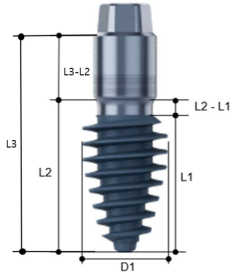
Based on the technological characteristic comparison tables below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

Dimensions of the implant (Subject and Predicate/references)

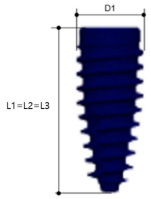
Not yet
BLUEDIAMOND IMPLANT



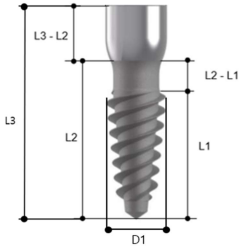
K231967
ARi ExCon Implant



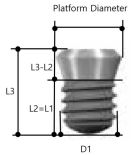
K182448
BLUEDIAMOND IMPLANT



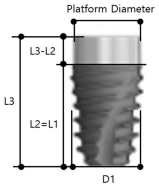
K210852
Noris Medical Dental Implants System -Cortical



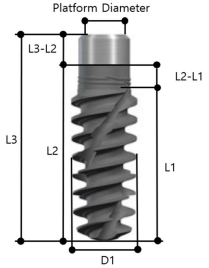
K202942
Straumann® 4 mm Short Implants



K213599
SuperLine -FXSxxxx Series



K200586
Straumann® TLX Implant System



	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3	Reference Device 4	Reference Device 5
510k	K241972	K231967	K182448	K210852	K202942	K213599	K200586
Device Name	**BLUEDIAMOND IMPLANT**	**ARi ExCon Implant**	**BLUEDIAMOND IMPLANT**	**Noris Medical Dental Implants System -Cortical**	**Straumann® 4 mm Short Implants**	**SuperLine -FXSxxxx Series**	**Straumann® TLX Implant System**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Noris Medical LTD	Straumann USA, LLC	Dentium Co., Ltd.	Straumann USA, LLC
Indication for use	The BLUEDIAMOND IMPLANT 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 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 ARi ExCon 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 in the following situations and with the clinical protocols: - Delayed loading - Immediate loading when good primary stability is	The BLUEDIAMOND IMPLNAT 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.	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. The 4 mm Short Implants are specifically recommended for:	SuperLine® implants are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine® implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length implants are indicated for delayed loading.	TLX Dental Implant: Straumann TLX Implants are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth and multi-unit restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.

	For the BLUEDIAMOND IMPLANTS with a Thread Length of 5mm, It is indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. It is specifically recommended for: - Fixed partial dentures/splinted units (one implant per unit) - Pontic cases in combination with at least one longer implant - Fully edentulous cases with at least one 5 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants	achieved and with appropriate occlusal loading.	Lager implats are dedicated for the molar region.		- Fixed partial dentures/splinted units (one implant per unit) - Pontic cases in combination with at least one longer implant - Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants		
Design							
Widest Thread Diameter (D1, mm) X Total Length (L3, mm)	· Normal Thread Ø 4.0 x 9.0, 11.0, 13.0, 15.0 Ø 4.4 x 7.0, 9.0, 11.0, 13.0, 15.0 Ø 4.7 x 7.0, 9.0, 11.0, 13.0, 15.0 · Deep Thread Ø 4.4 x 9.0, 11.0, 13.0, 15.0 Ø 4.8 x 7.0, 9.0, 11.0, 13.0, 15.0 Ø 5.1 x 7.0, 9.0, 11.0, 13.0, 15.0	· Normal Thread Ø 3.8 x 11.0, 13.0, 15.0 Ø 4.3 x 11.0, 13.0, 15.0 Ø 4.8 x 11.0, 13.0, 15.0 Ø 5.3 x 11.0, 13.0, 15.0 · Deep Thread Ø 4.3 x 11.0, 13.0, 15.0 Ø 4.8 x 11.0, 13.0, 15.0 Ø 5.3 x 11.0, 13.0, 15.0 Ø 5.8 x 11.0, 13.0, 15.0	· 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	Ø4.0 X 11.5, 13.0, 16.0, 18.0, 20.0 Ø5.0 X 11.5, 13.0, 16.0 Ø6.0 X 11.5, 13.0, 16.0	Ø4.1 x 5.8* Ø4.8 x 5.8*	Ø3.6 x 7.0 Ø4.0 x 7.0 Ø4.5 x 7.0 Ø5.0 x 7.0 Ø5.0 x 7.0 Ø5.8 x 7.0	Ø 3.75 x 7.8, 8.8, 11.8, 13.8, 15.8, 17.8, 19.8* Ø 4.0 x 7.8, 8.8, 11.8, 13.8, 15.8, 17.8, 19.8* Ø 4.5 x 7.8, 8.8, 11.8, 13.8, 15.8, 17.8, 19.8* Ø 5.0 x 7.8, 8.8, 11.8, 13.8, 15.8, 17.8, 19.8* Ø 5.5 x 7.8, 8.8, 11.8, 13.8* Ø 6.5 x 7.8, 8.8, 11.8, 13.8*
Threaded Length (L1, mm)	· Normal Thread Ø 4.0: 7.0, 9.0 Ø 4.4: 5.0, 7.0, 9.0 Ø 4.7: 5.0, 7.0, 9.0 · Deep Thread Ø 4.4: 7.0, 9.0 Ø 4.8: 5.0, 7.0, 9.0 Ø 5.1: 5.0, 7.0, 9.0	For all diameters: 7.0, 9.0	For all diameters: 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2	Ø 4.0: 6.8, 8.0, 10.0, 11.0, 12.5 Ø 5.0: 6.8, 8.0, 10.0 Ø 6.0: 6.8, 8.0, 10.0	For all diameters: 4.0	For all diameters: 5.5	Ø 3.75: 5.0, 7.0, 8.3, 10.3, 12.3, 14.0, 16.0* Ø 4.0: 5.0, 7.0, 8.3, 10.3, 12.3, 14.0, 16.0* Ø 4.5: 5.0, 7.0, 8.3, 10.3, 12.3, 14.0, 16.0* Ø 5.0: 5.0, 7.0, 8.3, 10.3, 12.3, 14.0, 16.0* Ø 5.5: 5.0, 7.0, 8.3, 10.3* Ø 6.5: 5.0, 7.0, 8.3, 10.3*
Implanted Length (L2, mm) (Length within the bone)	· Normal Thread Ø 4.0: 8.0, 9.0, 10.0, 11.0 Ø 4.4: 7.0, 8.0, 9.0, 10.0, 11.0 Ø 4.7: 7.0, 8.0, 9.0, 10.0, 11.0 · Deep Thread Ø 4.4: 8.0, 9.0, 10.0, 11.0 Ø 4.8: 7.0, 8.0, 9.0, 10.0, 11.0 Ø 5.1: 7.0, 8.0, 9.0, 10.0, 11.0	For all diameters: 8.0, 9.0, 10.0, 11.0	For all diameters: 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2	Ø 4.0: 7.5, 9.0, 12.0,14.0, 16.0 Ø 5.0: 7.5, 9.0, 12.0 Ø 6.0: 7.5, 9.0, 12.0	For all diameters: 4.0	For all diameters: 5.5	Ø3.75, 4.0, 4.5, 5.0: 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0 Ø5.5, 6.5: 6.0, 8.0, 10.0, 12.0

Gingival (Cuff) Height (L3-L2, mm)	2.0, 3.0, 4.0	3.0, 4.0	N/A	4.0	1.8*	1.5	1.8*
Thread to Shoulder Height (L2-L1, mm)	1.0, 2.0	1.0, 2.0	N/A	0.7, 1.0, 2.0, 3.0, 3.5	N/A	N/A	1.0, 1.7, 2.0*
Implant to Abutment Connection	Internal Octa	External Hex	Internal Octa	Internal Hex	Internal	Tapered conical hex	TorcFit (with conical fitting)
Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	Titanium alloy	Roxolid® (Ti-Zr alloy)	All implants: unalloyed titanium, ASTM F67	Titanium Grade 4
Surface Treatment	Sand-blasted, Large grit, Acid-etched (S.L.A) Machined collar	Sand-blasted, Large grit, Acid-etched (S.L.A) Machined collar	Sand-blasted, Large grit, Acid-etched (S.L.A)	RBM (Resorbable Balsting Media)	SLActive®	All implants: S.L.A., Al2O3 blasted and acid etched	Hydrophilic SLActive®
Sterilization	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation
Shelf Life	5 Years	5 Years	5 Years	5 Years	5 Years	Unknown	5 Years
Type	Tissue level Implant	Tissue level Implant	Bone level Implant	Tissue level Implant	Tissue level Implant	Tissue level Implant	Tissue level Implant
Feature	- Tapered body - 0.8mm thread pitch	- Tapered body - 0.8mm thread pitch	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8mm thread pitch	- Tapered body - Threaded	-	-	-

* Dimensional information not found in the 510(k) Summary for each reference device was taken from the published catalog for that device.

Substantial Equivalence Discussion

1. Similarities

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

- Indication for Use, Design, Thread to shoulder Height, Implant to Abutment Connection, Material, Surface Treatment and Sterilization, Shelf-life, Type and Feature.

2. Differences

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

- Widest Thread Diameter, Total Length

The Widest Thread Diameter and Total Length of subject device is slightly different with predicate device but all the dimensions of subject device lie within range of predicate device.

- Threaded Length

The Threaded Length of subject device is slightly different with predicate device. But, all dimensions of subject device lie within range of Predicate/Reference devices.

- Implanted Length

The Implanted Length of subject device is slightly different with predicate device. But, all dimensions of subject device lie within range of Predicate/Reference devices.

- Gingival (Cuff) Height

The Gingival (Cuff) Height of subject device is slightly different with predicate device. But, all dimensions of subject device lie within range of Predicate/Reference devices, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

The proposed Cuff type of BLUEDIAMOND IMPLANT has common in all the terms in the comparison chart except the Widest Thread Diameter, Total Length, Threaded Length, Implanted Length and Gingival (Cuff) Height. But all dimensions of subject device lie within range of Predicate/Reference devices. Therefore, these differences don't affect the device's fundamental functions, safety and effectiveness

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".

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 BLUEDIAMOND IMPLANT system since the BLUEDIAMOND IMPLANT system has same material composition, manufacturing process and patient contacting parts as the previously cleared device, XPEED AnyRidge Internal System (K122231), BLUEDIAMOND Implant System (K182448) and AnyRidge Internal Implant System (K110955).

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

The BLUEDIAMOND IMPLANT is supplied in sterile state. Sterilization validating testing has been performed in accordance with ISO 11137 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. The subject device is evaluated with previous device which was evaluated under the previous 510(k) submission, K122231. 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.

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 and manufacturing process with the previously our cleared devices of XPEED AnyRidge Internal System (K122231) for the surface treatment of S.L.A.

Performance test

The Fatigue 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.

The surface area analysis and pullout testing were performed on the subject 5 mm threaded length implants, and compared to predicates.

MR Compatibility

The MR compatibility was performed to access the risk of exposing patients who have implantable medical devices according to FDA's guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment".

An assessment was made to demonstrate that the subject devices do not configure a new worst case and can be represented by the previously conducted studies reviewed for reference devices obtained the status of MR Conditional per K230618. Therefore, the subject devices are MR conditional devices and a patient treated with the subject devices can be safely scanned observing the parameters previously established per reference devices.

9. Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the subject device is substantially equivalent to the predicate and reference devices.