January 13, 2025

MegaGen Implant Co., Ltd.
Back Kyung-Hee
Official Correspondent
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K242030
Trade/Device Name: MegaGen Dental Implant Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 12, 2024
Received: December 12, 2024

Dear Back Kyung-Hee:

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)*

K242030

Device Name

MegaGen Dental Implant Abutment

Indications for Use *(Describe)*

MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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.

All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
For MegaGen Dental Implant Abutment (K242030)

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

Date: January 08, 2025

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

Kyung-Hee, Back
MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
Daegu, Republic of Korea
Tel: +82-53-222-3864 Fax: +82-53-247-2254
Email: ra9@imegagen.com

3. Device

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

4. Predicate Device

- **Primary Predicate Device:**
  K233450 MegaGen Dental Implant Abutment

- **Reference Devices:**
  K110955 AnyRidge Internal Implant System
  K123988 AnyOne Internal Implant System
  K182448 BLUEDIAMOND IMPLANT System
  K203554 AnyOne External Implant System
  K203808 Multi-unit Abutment System
  K230618 MegaGen Dental Implant Systems Portfolio - MR Conditional
  K231967 ARi ExCon Implant System
  K220562 TiGEN, ZrGEN, Scan Healing Abutment

5. Description

- **Healing Abutment**

The Healing Abutment helps to form suitable emergence profile during period of gingival healing. It is used for non-submerged type surgery or for two-stage surgery. It is made of Ti-6Al-4V-ELI and offered in machined surface. The Healing Abutment is sterilized using irradiation during manufacturing process and intended for single use.

The dimensions of Healing Abutment are follows:

Device	Component
Healing Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.2, 5.2, 6.2, 7.2 x 13.4, 14.4 mm **AnyOne Internal Implant System** Ø 4.2, 4.7, 5.7, 6.7 x 14.2, 15.2 mm

The Healing Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3

- **Temporary Cylinder**

The Temporary Cylinder is used in conjunction with Abutment to provide support for provisional restoration. It is connected to the Abutment with Cylinder Screw. It is made of POM and offered in machined surface. The Temporary Cylinder is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Temporary Cylinder are follows:

Device	Component
Temporary Cylinder	**Common** Ø 5.0 x 10.0 mm

- **EZ Post Abutment**

The EZ Post Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis. It is made of Ti-6Al-4V-ELI, and offered in anodizing. The EZ Post Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of EZ Post Abutment are follows:

Device	Component
EZ Post Abutment	**AnyOne Internal Implant System** Ø 4.5, 5.5, 6.5 x 11.2, 12.2, 13.2, 14.2, 15.2 mm

The EZ Post Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3

- **EZ Post Cylinder**

The EZ Post Cylinder is used in conjunction with Multi-unit Abutment to provide support cement and screw type final prosthesis. It is connected to the Abutment with Cylinder Screw. It is made of Ti-6Al-4V-ELI, and offered in machined surface. The EZ Post Cylinder is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of EZ Post Cylinder are follows:

Device	Component
EZ Post Cylinder	**Common** Ø 4.8 x 4.5, 6.0, 7.0 mm

- **CCM Abutment**

The CCM Abutment is used in conjunction with fixture and connected to the Fixture with Multi Post Screw. The CCM Abutment is available to cast with non-precious metal alloys (Co-Cr-Mo alloy). The CCM Cuff connected with Fixture is made of CO-Cr-Mo alloy, and CCM Sleeve covered with final prosthesis is made of plastic (POM), which has grooved surface to allow better retention of resin or wax. The plastic part will be removed after casting. The CCM Abutment is not machinable and is the final prosthesis. The CCM Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of CCM Abutment are follows:

Device	Component
CCM Abutment	**XPEED AnyRidge Internal Implant System** Ø 3.8 x 14.7 mm

The CCM Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4

- **Gold Abutment**

The Gold Abutment is used in conjunction with fixture and connected to the Fixture with Multi Post Screw. The Gold Abutment is available to cast with precious metal alloys (Gold alloy). The Gold Cuff connected with Fixture is made of gold alloy, and Gold Sleeve covered with final prosthesis is made of plastic (POM), which has grooved surface to allow better retention of resin or wax. The plastic part will be removed after casting. The Gold Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Gold Abutment are follows:

Device	Component
Gold Abutment	**XPEED AnyRidge Internal Implant System** Ø 3.8 x 14.7 mm

The Gold Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4

- **Octa Abutment**

The Octa Abutment is used for fabricating screw-retained prosthesis. It is one-piece type. The lower part has a male screw to place into the fixture, and the top part has a female screw to connect Cylinders or ZrGEN Abutment of Octa type with Abutment Screw to fabricate temporary or final prosthesis. It is made of Ti-6AI-4V-ELI, and offered in anodizing. The Octa Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Octa Abutment are follows:

Device	Component
Octa Abutment	**XPEED AnyRidge Internal Implant System** Ø 3.8, 4.8, 5.8 x 8.0, 9.0, 10.0, 11.0, 12.0 mm

The Octa Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4

- **ZrGEN Abutment**

The ZrGEN Abutment is a two-piece abutment composed of the stock titanium base cemented together with the zirconia top-half to complete the final finished device. It is made of Ti-6Al-4V ELI. It is provided with abutment screw. All ZrGEN Abutment is provided non-sterile. Therefore, the ZrGEN Abutment must be sterilized by users prior to use.

The dimensions of ZrGEN Abutment are follows:

Device	Component
ZrGEN Abutment	**XPEED AnyRidge Internal Implant System** **Standard Type** - Ø 4.0, 4.4 x 7.7, 8.6, 9.2, 10.1, 11.1, 11.2, 11.6, 12.1, 12.6, 13.3, 14.6 mm **AnyOne Internal Implant System** **Standard Type -** Ø 4.0, 4.4 x 8.0, 8.9, 9.5, 10.4, 11.4, 11.5, 11.9, 12.4, 12.9, 13.9, 14.9 mm **ST Internal Implant System** **C-Type -** Ø 4.3, 5.5 x 8.0, 8.15, 8.5, 8.65, 9.5, 9.65 mm **Standard Type** - Ø 4.0, 4.4 x 7.8, 7.9, 8.0, 8.7, 8.8, 9.3, 9.4, 10.2, 10.3, 11.3, 11.4, 11.7, 11.8, 12.2, 12.3, 12.7, 12.8, 13.7, 13.8, 14.7, 14.8 mm **Common** **Octa Type** - Ø 5.0, 5.5, 6.5 x 5.8, 6.8, 8.8 mm

The allowable ranges of design parameters are follows:

Titanium base	**Minimum wall thickness (mm)**	0.123, 0.3225, 0.5
	Maximum angulation (°)	0
	Minimum gingival collar (ø)	3.00, 3.15, 3.40, 4.05, 4.25, 5.25,
	Maximum gingival collar (ø)	4.00, 4.30, 4.40, 5.00, 5.50, 6.50
	Minimum post height (mm) *	3.20, 3.70, 4.70, 6.70
	Maximum post height (mm) *	4.50, 4.70, 5.00, 6.00, 8.00

***** Post height for single-unit restoration is defined as the cementable post measured above the gingival collar of the final abutment design.

The allowable ranges of design parameters for Zirconia top-half after CAD/CAM patient-matching are follows:

Zirconia top-half	**Minimum wall thickness (mm)**	0.5
	Maximum angulation (°)	0
	Minimum gingival collar (ø)	8
	Maximum gingival collar (ø)	10
	Minimum Gingival collar height (mm)	2
	Maximum Gingival collar height (mm)	5
	Minimum post height (mm)	7
	Maximum post height (mm)	15

The ZrGEN Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3
	ST Internal Implant System	ST Internal Fixture	K192347	Internal Hex	3.7, 4.2, 4.7, 5.2, 6.2, 7.2

- **TiGEN Abutment**

The TiGEN Abutment is machined with the final prosthetic in accordance with the intraoral structure. It is machined by using dental CAD/CAM technology in accordance with customized patient's information in MegaGen-validated milling center. The TiGEN Abutment is made of Ti-6Al-4V ELI. And It is provided with abutment screw. All TiGEN Abutment is provided non-sterile. The milled TiGEN Abutment must be sterilized by users prior to use.

The dimensions of TiGEN Abutment are follows:

Device	Component
TiGEN Abutment	**ST Internal Implant System** Ø 10.0, 12.0 x 28.55, 28.70, 28.85 mm

The allowable ranges of design parameters after CAD/CAM patient-matching are follows:

Standard Type	**Minimum wall thickness (mm)**	0.25
	Maximum angulation (°)	30
	Minimum gingival collar (ø)	4.00
	Maximum gingival collar (ø)	9.50, 11.50
	Minimum Gingival collar height (mm)	0.50
	Maximum Gingival collar height (mm)	5.00
	Minimum post height (mm) *	4.00
	Maximum post height (mm) *	6.00

***** Post height for single-unit restoration is defined as the cementable post measured above the gingival collar of the final abutment design.

The TiGEN Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	ST Internal Implant System	ST Internal Fixture	K192347	Internal Hex	3.7, 4.2, 4.7, 5.2, 6.2, 7.2

- **AXA Abutment**

1) Straight Type

The AXA Abutment of straight type is a one-piece type. The AXA Abutment is intended only for multi-unit loaded restoration. It is made of Ti-6Al-4V-ELI and offered in anodizing gold. The AXA Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

2) Angled Type

The AXA Abutment of angled type is two-piece type. The AXA Abutment is intended only for multi-unit loaded restoration. It is made of Ti-6Al-4V-ELI and offered in anodizing gold. They are available in 12˚, 20˚ and 30˚ angles, and offers one type (Hex type). The AXA Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of AXA Abutment are follows:

Device	Component
AXA Abutment	**ARi ExCon Implant System** **Straight Type** - Ø 4.2 x 7.5, 8.5, 9.5, 10.5, 11.5 mm **Angled Type** - Ø 4.2, 4.75 x 5.865, 6.349, 6.65, 6.865, 7.349, 7.65, 7.865, 8.349, 8.65, 8.865, 9.349, 9.65 mm x 12˚, 20˚, 30˚

The AXA Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	ARi ExCon Implant System	ARi ExCon Implant	K231967	External Hex	3.8, 4.3, 4.8, 5.3, 5.8

- **Abutment Screw**

The Abutment Screw is used for securing the abutment to the endosseous implant. It is made of Ti-6AI-4V-ELI and offered in anodizing gold and machined surface. The Abutment Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Abutment Screw are follows:

Device	Component
Abutment Screw	**ARi ExCon Implant System** Ø 2.2, 2.25, 2.3, 2.6 x 4.7, 5.2, 6.2, 7.2, 8.2, 9.2, 9.9 mm

6. Indications for use

MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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.

All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture

7. Basis for Substantial Equivalence

The MegaGen Dental Implant Abutment is 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. The size range of the subject of the subject device slightly differ from the predicate device however it is very minor not affecting substantial equivalence.

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.

(1) Healing Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K242030	K110955	K182448
Device Name	**Healing Abutment**	**Healing Abutment**	**Healing Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	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. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design			
Diameter (Ø, mm)	4.2, 4.7, 5.2, 5.7, 6.2, 6.7, 7.2	4.2, 5.2, 6.2, 7.2, 10.0	3.2, 4.2, 5.2, 6.2

Gingival Height (mm)	7.8, 8.5, 8.8, 9.5	3.5, 4.5, 5.5, 6.5, 7.5	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5
Total Length (mm)	13.4 ~ 15.2	8.4 ~ 14.4	8.6 ~ 15.6
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf-life	5 years	5 years	5 years
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System	AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

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

- Indications for Use, Design, Diameter, Gingival Height, Total Length, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Shelf Life

2. Difference

There are no differences with the Reference devices.

3. Discussion

The proposed Healing Abutment and reference devices have common in all items in the comparison, and can be considered practically equivalent.

(2) Temporary Cylinder

	Subject Device	Predicate Device	Reference Device
510(k) No.	K242030	K233450	K231967
Device Name	**Temporary Cylinder**	**Temporary Cylinder**	**Temporary Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	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 achieved and with appropriate occlusal loading.
Design			
Diameter (Ø, mm)	5.0	4.8, 4.9, 5.7	3.5, 4.0, 4.5, 5.0, 6.0
Gingival Height (mm)	2.3, 4.1, 6.1	3.0	2.0
Post Height (mm)	3.9, 6.9, 7.7	8.5	8.0, 10.0, 12.0
Total Length (mm)	10.0	12.0	10.0 ~ 14.0
Angulation (˚)	Straight	Straight	Straight
Connection Interface	Internal Non-Hex	Internal Non-Hex	External Hex
Material	POM (Delrin 100P NC010)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13), POM (Delrin 100P NC010)
Surface Treatment	Machined	Machined	Machined, Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Compatible Implant System	Common	XPEED AnyRidge Internal Implant System BLUEDIAMOND IMPLANT System	ARi ExCon Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device and/or reference device.

- Indications for Use, Design, Diameter, Total length, Angulation, Connection Interface, Surface Treatment, Material, Single Use and Sterilization

2. Differences

The subject device has the different characteristic for the followings compared to the Predicate device and/or reference device.

- Gingival Height

The Gingival Height of the subject device is slightly different with the predicate device. Some dimension (2.3mm) are within the range of the predicate device and reference device. Other dimensions (4.1mm and 6.1mm) are slightly longer than the predicate device. It does not cause a matter in substantial equivalence since the total length is within the range of the predicate and reference devices, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Post Height

The Post Height of the subject device is slightly different with the predicate device. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

3. Discussion

The proposed Temporary Cylinder and predicate device have common in all items in the comparison chart except the Gingival Height and Post Height. These differences are not affect device's substantial equivalence. Also, the subject device is intended for temporary use.

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

(3) EZ Post Abutment

	Subject Device	Predicate Device	Reference Device
510(k) No.	K242030	K233450	K110955
Device Name	**EZ Post Abutment**	**EZ Post Abutment**	**EZ Post Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø, mm)	4.5, 5.5, 6.5	4.0, 5.0, 6.0, 7.0	4.0, 5.0, 6.0, 7.0
Gingival Height (mm)	1.5, 2.5, 3.5, 4.5	0.8, 1.8, 2.8, 3.8, 4.8	1.8, 2.8, 3.8, 4.8
Post Height (mm)	7.0	4.0, 5.5, 7.0	5.5, 7.0
Total Length (mm)	11.2 ~ 15.2	6.15 ~ 13.15	7.85 ~ 16.35
Angulation (˚)	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex	Internal Octa	Internal Hex, Internal Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Compatible Implant System	AnyOne Internal Implant System	BLUEDIAMOND IMPLANT System	AnyRidge Internal Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device and/or reference device.

- Indications for Use, Design, Post Height, Total Length, Connection Interface, Angulation, Material, Surface Treatment, Single Use and Sterilization

2. Differences

The subject device has the different characteristic for the followings compared to the Predicate device and/or reference device.

- Diameter

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

- Gingival Height

The Gingival Height of the subject device is slightly different with the predicate device, but all of diameter lie within range of the predicate device and reference device.

3. Discussion

The proposed EZ Post Abutment and Predicate device have common in all items in the comparison chart except Diameter and Gingival Height. These differences are explained not affecting on device's fundamental functions and safety. Also, the proposed product is straight type abutment, the fatigue test was performed as a representative of the worst case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate and reference devices.

(4) EZ Post Cylinder

	Subject Device	Predicate Device
510(k) No.	K242030	K233450
Device Name	**EZ Post Cylinder**	**EZ Post Cylinder**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture
Design		
Diameter (Ø, mm)	4.8	4.8, 4.9, 5.7
Total Length (mm)	4.5 ~ 7.0	4.2 ~ 9.0
Angulation (˚)	Straight	Straight
Connection Interface	Internal Non-Hex	Internal Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined, Anodizing
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System ST Internal Implant System ARi ExCon Implant System	XPEED AnyRidge Internal Implant System BLUEDIAMOND IMPLANT System AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

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

- Indications for Use, Design, Diameter, Total Length, Angulation, Connection Interface, Material, Surface Treatment, Single Use, and Sterilization

2. Difference

There are no differences with the Predicate device.

3. Discussion

The proposed EZ Post Cylinder and predicate device have common in all items in the comparison, and can be considered practically equivalent.

(5) CCM Abutment

	Subject Device	Reference Device
510(k) No.	K242030	K182448
Device Name	**CCM Abutment**	**CCM Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	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. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design		
Diameter (Ø, mm)	3.8	3.8
Post Height (mm)	11.0	11.6
Total Length (mm)	14.7	14.65 ~ 16.15
Angulation (˚)	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex	Internal Octa, Internal Non-Octa
Material	Body: Co-Cr-Mo alloy Sleeve: POM (Delrin 100P NC010)	Body: Co-Cr-Mo alloy Sleeve: POM (Delrin 100P NC010)
Surface Treatment	N/A	N/A
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Compatible Implant System	XPEED AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

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

- Indication for use, Design, Diameter, Angulation, Material, Surface Treatment, Single Use and Sterilization

2. Differences

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

- Post Height

The Post Height of subject device is slightly smaller than the prior cleared reference device. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Total Length

The Total Length of subject device is slightly different with the reference device, but the total length lies within range of cleared reference device. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.

- Connection Interface

The connection interface depends on the compatible implant system. Both features of Octa and Hex provides anti-rotational feature.

3. Discussion

The proposed CCM Abutment and Reference device have common in all items in the comparison chart except the Post Height, Total Length and Connection Interface. These differences are explained not affecting on device's fundamental functions and

safety. Also, the proposed product is straight type abutment, the fatigue test was performed as a representative of the worst-case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference device.

(6) Gold Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K242030	K203554	K123988
Device Name	**Gold Abutment**	**Gold Abutment**	**Gold Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The AnyOne External Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø, mm)	3.8	4.0, 4.5, 5.5	4.5
Post Height (mm)	11.0	10.0	11.0
Total Length (mm)	14.7	11.0, 11.2	15.7
Angulation (˚)	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex	External Hex, External Non-Hex	Internal Hex, Internal Non-Hex
Material	Body: Gold alloy Sleeve: POM (Delrin 100P NC010)	Body: Gold alloy Sleeve: POM (Delrin 100P NC010)	Body: Gold alloy Sleeve: POM (Delrin 100P NC010)
Surface Treatment	N/A	N/A	N/A
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Compatible Implant System	XPEED AnyRidge Internal Implant System	AnyOne External Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

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

- Indication for use, Design, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization

2. Differences

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

- Diameter

The Diameter of subject device is slightly smaller than the prior cleared reference devices. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Total Length

The Total Length of subject device is slightly different with the reference device 1, but the total length lies within range of cleared reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.

3. Discussion

The proposed Gold Abutment and Reference devices have common in all items in the comparison chart except the Diameter and

Total Length. These differences are explained not affecting on device's fundamental functions and safety. Also, the proposed product is straight type abutment, the fatigue test was performed as a representative of the worst-case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference devices.

(7) Octa Abutment

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	K242030	K182448	K110955
Device Name	**Octa Abutment**	**Octa Abutment**	**Octa Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	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. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø, mm)	3.8, 4.8, 5.8	3.8, *4.8, *5.8	4.8
Gingival Height (mm)	0.8, 1.8, 2.8, 3.8, 4.8	0.8, 1.8, 2.8, 3.8, 4.8	2.0, 3.0, 4.0, 5.0
Total Length (mm)	8.0 ~ 12.0	7.85 ~ 14.85	9.0 ~ 12.0
Angulation (˚)	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Compatible Implant System	XPEED AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System	AnyRidge Internal Implant System

Substantial Equivalence Discussion

1. Similarities

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

- Indications for Use, Design, Diameter, Gingival Height, Total Length, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization

2. Differences

There are no differences with the Reference devices.

3. Discussion

The proposed Octa Abutment and Reference devices have common in all the terms in the comparison, and can be considered practically equivalent.

Fatigue testing was conducted on the proposed Octa Abutment because it is the worst-case model within a compatible implant system (XPEED AnyRidge Internal Implant System). The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

*****The Octa Abutment diameter for K182448, which has previously been cleared by the FDA, was not identified in the 510(k) Summary, but was included in the submitted document and has been added.

(8) ZrGEN Abutment

	Subject Device	Reference Device
510(k) No.	K242030	K220562
Device Name	**ZrGEN Abutment**	**ZrGEN Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. For TiGEN Abutment and ZrGEN Abutment, all digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture.
Design		
Diameter (Ø, mm)	4.0, 4.3, 4.4, 5.0, 5.5, 6.5	3.1, 3.9, 4.0, 4.3, 4.4, 4.5, 5.0, 5.5, 6.0, 6.5
Total Length (mm)	5.8 ~ 14.9	5.1 ~ 16.55
Top-half Material	Zirconia ISO13356	Zirconia ISO13356
Range of Top-half Design Parameter (mm)	Diameter: Min 8.0 Gingival Collar Height: Min 2.0 Post Height: 7.0	Diameter: Min 8.0 Gingival Collar Height: Min 2.0 Post Height: 7.0
Angulation (˚)	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex Internal Octa, Internal Non-Octa	Internal, External
Metallic Base Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined
Single Use	Yes	Yes
Sterilization	Non-Sterile	Non-Sterile
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System ST Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

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

- Indications for Use, Design, Diameter, Total Length, Top-half Material, Range of Top-half Design Parameter, Angulation, Connection Interface, Metallic Base Material, Surface Treatment, Single Use, and Sterilization

2. Difference

There are no differences with the Reference device.

3. Discussion

The proposed ZrGEN Abutment and reference device have common in all the terms in the comparison, and can be considered practically equivalent.

The octa type of ZrGEN Abutment compatible with XPEED AnyRidge Internal Implant System is an abutment connected to the proposed Octa Abutment, the worst model in the implant system so a fatigue test was conducted the proposed Octa abutment.

In addition, fatigue testing was conducted on the ZrGEN Abutment compatible with AnyOne Internal Implant System because it is

the worst model within the compatible implant system. The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

(9) TiGEN Abutment

	Subject Device	Reference Device
510(k) No.	K242030	K220562
Device Name	**TiGEN Abutment**	**TiGEN Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. For TiGEN Abutment and ZrGEN Abutment, all digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture.
Design		
Diameter (Ø, mm)	10.0, 12.0	10.0, 12.0
Total Length (mm)	28.70, 28.85	26.00 ~ 30.55
Angulation (˚)	Up to 30˚	Up to 30˚
Connection Interface	Internal Hex, Internal Non-Hex	Internal, External
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing
Single Use	Yes	Yes
Sterilization	Non-Sterile	Non-Sterile
Compatible Implant System	ST Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

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

- Indications for Use, Design, Diameter, Total Length, Angulation, Connection Interface, Material, Surface Treatment, Single Use, and Sterilization

2. Difference

There are no differences with the Reference device.

3. Discussion

The proposed TiGEN Abutment and reference device have common in all the terms in the comparison, and can be considered practically equivalent. Also, fatigue testing was conducted on the TiGEN Abutment compatible with ST Internal Implant System because it is the worst model within the compatible implant system. The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

(10) AXA Abutment – Straight Type

	Subject Device	Predicate Device	Reference Device
510(k) No.	K242030	K233450	K203808
Device Name	**AXA Abutment**	**AXA Abutment (Straight)**	**Multi-unit Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø, mm)	4.2	4.0, 5.0	4.8
Gingival Height (mm)	2.0, 3.0, 4.0, 5.0, 6.0	1.8, 2.8, 3.8, 5.8, 7.8	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5
Post Height (mm)	4.0	4.0, 6.0	1.8, 2.2
Total Length (mm)	7.5 ~ 11.5	11.05 ~ 20.1	6.2 ~ 12.84
Angulation (˚)	Straight	Straight	Straight
Connection Interface	Internal Conical Connection	Internal Hex, Internal Non-Hex, Internal Conical Connection	Internal Hex, Internal Non-Hex, Internal Conical Connection
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing, Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Compatible Implant System	ARi ExCon Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device and/or reference device.

- Indications for Use, Design, Post Height, Total Length, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization

2. Differences

The subject device has the different characteristic for the followings compared to the Predicate device and/or reference device.

- Diameter

The Diameter of the subject device is slightly different with the predicate device, but this diameter lies within range of the predicate device.

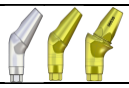
- Gingival Height

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

3. Discussion

The proposed AXA Abutment and Predicate device have common in all the terms in the comparison chart except Diameter and Gingival Height. These differences are explained not affecting on device's fundamental functions and safety. Also, the proposed product is straight type abutment, the fatigue test was performed as a representative of the worst-case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference devices.

(11) AXA Abutment – Angled Type

	Subject Device	Predicate Device	Reference Device
510(k) No.	K242030	K233450	K203808
Device Name	**AXA Abutment**	**AXA Abutment (Angled)**	**Multi-unit Angled Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø, mm)	4.2, 4.75	4.0, 5.0	4.8, 5.0
Gingival Height (mm)	3.0, 3.1, 4.0, 4.1, 5.0, 5.1, 6.0, 6.1	3.8, 5.8, 7.8	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5
Post Height (mm)	4.0	2.0, 4.0, 6.0	2.2, 3.9
Total Length (mm)	5.865 ~ 9.65	6.4 ~ 10.85	3.4 ~ 8.85
Angulation (˚)	12°, 20°, 30°	20°, 30°	17°, 29°, 30°
Connection Interface	External Hex	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Anodizing	Anodizing, Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Additional Post Component	EZ Post Cylinder	EZ Post Cylinder	Yes
Compatible Implant System	ARi ExCon Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device and/or reference device.

- Indications for Use, Design, Post Height, Material, Surface Treatment, Single Use and Sterilization

2. Differences

The subject device has the different characteristic for the followings compared to the Predicate device and/or reference device.

- Diameter

The Diameter of the subject device is slightly different with the predicate device, but this diameter lies within range of the predicate device.

- Gingival Height

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

- Total Length

The Total Length of the subject device is slightly different with the predicate device. But all total lengths lie within range of the predicate device and reference device.

- Angulation

The angles of the subject device are 12°, 20° and 30°, 20° and 30° angle are same as the predicate device. 12° angle is slightly different from the predicate device, but the variety of the angle can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Connection Interface

The connection interface depends on the compatible implant system.

3. Discussion

The proposed AXA Abutment and Predicate device have common in all the terms in the comparison chart except Diameter, Gingival Height, Total length and Angulation. These differences are explained not affecting on device's fundamental functions and safety. Also, the fatigue test was performed on the subjected AXA Abutment (Angled Type) as the representative model for the worst case with an angle to confirm the substantial equivalence. The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

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

(12) Abutment Screw

	Subject Device	Predicate Device
510(k) No.	K242030	K233450
Device Name	**Abutment Screw**	**Abutment Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.
Design		
Diameter (Ø, mm)	2.2, 2.25, 2.3, 2.6	2.0, 2.1, 2.2
Total Length (mm)	4.7 ~ 9.9	7.9 ~ 12.7
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined, Anodizing
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Compatible Implant System	ARi ExCon Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System

Substantial Equivalence Discussion

1. Similarities

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

- Indication for use, Design, Material, Surface Treatment, Single Use and Sterilization

2. Differences

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

- Diameter

The Diameter (2.2 mm) of the subject device is same as the predicate device. Other diameters (2.25, 2.3 and 2.6 mm) are slightly longer than the predicate device, but the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Total Length

The Total Length of the subject device is slightly different with the predicate device, but it does not cause a matter in substantial equivalence since the size differences are very minor.

3. Discussion

The proposed Abutment Screw and Predicate device have common in all the terms in the comparison chart except Diameter and Total length. These differences are explained not affecting on device's fundamental functions and safety. 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 biocompatibility of the subject device was performed through cleared K110955, K123988 and K210161, which has same materials and manufacturing process.

Sterilization validation

The Healing Abutment is provided as sterile devices. The Sterilization validating testing has been performed in accordance with ISO 11137 to verify the sterility assurance level (10^{-6}) under the previous 510(k) submission, K220562. 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 sterilization validation of the supplied sterile subject device can be leveraged with prior cleared reference device, K220562.

The subject devices excluding the sterile device are supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}). Validation Testing was conducted on a worst-case test article from our previously cleared reference device, K220562, E220672, K210161, K123988.

Accelerated shelf life Test

The accelerated shelf life study was performed in accordance with ASTM F1980 and it was leveraged from the prior cleared Healing Abutment of 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>.

Performance Testing

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

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 MegaGen Dental Implant Abutment is substantially equivalent to the predicate device as here.