November 10, 2022

MegaGen Implant Co., Ltd.
% Hyo-Eun Lee
Assistant Research Engineer
DaeGyeong Regulatory Affairs Institute
32, Innovalley-ro
Daegu, Dong-gu 41065
REPUBLIC OF KOREA

Re: K220562
Trade/Device Name: TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 7, 2022
Received: October 11, 2022

Dear Hyo-Eun Lee:

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K220562

Device Name
TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment

Indications for Use *(Describe)*
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.

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 K220562

Date: Nov 09, 2022

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: Fax: +82-53-289-3420
Email: ra7@imegagen.com

3. Device

• Trade Name	TiGEN Abutment, ZrGEN Abutment and Scan Healing 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:**
K150203 Medentika CAD/CAM Abutments

• **Reference Device:**
K122231 XPEED AnyRidge Internal Implant System
K123988 AnyOne Internal Implant System
K150537 MiNi Internal Implant System
K171622 Dentium Ti-Base
K110955 AnyRidge Internal Implant System
K173374 TSV™ BellaTek® Encode® Healing Abutments
K182448 AnyRidge Octa 1 Implant System

5. Description

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 alloy. 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:

Standard Type	**Total length (mm)**	28.00, 28.40, 28.60, 28.70, 28.90, 29.05, 30.55
	Diameter (mm)	10.00, 12.00
Octa level Type	**Total length (mm)**	26.00
	Diameter (mm)	10.00, 12.00

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

Standard Type	**Minimum wall thickness (mm)**	0.47
	Maximum angulation (°)	30
	Minimum gingival collar height (mm)	2.00
	Maximum gingival collar height (mm)	5.00
	Minimum gingival collar (ø)	3.50, 4.00, 4.50
	Maximum gingival collar (ø)	9.50, 11.50
	Minimum post height (mm)	4.00
	Maximum post height (mm)	6.00, 6.50
Octa level Type	**Minimum wall thickness (mm)**	0.47
	Maximum angulation (°)	30
	Minimum gingival collar (ø)	4.00
	Maximum gingival collar (ø)	9.50, 11.50
	Minimum post height (mm)	4.00
	Maximum post height (mm)	6.00

The TiGEN Abutment is compatible with following MEGAGEN Implants and Screw cleared under:

Type	**Dental Implant**				**Octa Abutment**		**Screw**	
	Name	**The widest diameter (mm)**	**Platform Diameter (mm)**	**510(k) Number**	**Connection Diameter (mm)**	**510(k) Number**	**510(k) Number**	**Model Name**
Standard Type	XPEED AnyRidge Internal Fixture	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	2.31, 2.8, 3.1, 3.3	K122231, K123870, K140091	-	-	K110955	AANMSF
	AnyOne Internal Fixture	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3		K123988	-	-	K123988	AS20
	MINi Internal Fixture	3.0, 3.4		K150537	-	-	K150537	MIAS14
	AnyRidge Octa 1 Fixture	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5		K182448	-	-	K182448	AROAS16B, AROAS16
Octa Level Type	XPEED AnyRidge Internal Fixture	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	3.8, 4.0, 4.8, 5.0, 5.8, 6.0	K122231, K123870, K140091	4.0, 5.0, 6.0	K110955	K123988	IRCS200
	AnyOne Internal Fixture	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3		K123988	3.8, 4.8, 5.8	K123988		
	AnyRidge Octa 1 Fixture	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5		K182448	4.0, 5.0, 6.0	K182448		

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. This abutment is to be used only with implants placed straight. It is made of Ti-6Al-4V ELI alloy. 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 after the cementation of the Zirconia top-half.

The dimensions of ZrGEN Abutment are follows:

Standard Type	**Total length (mm)**	5.10, 5.50, 7.50, 7.70, 8.00, 8.15, 8.40, 8.60, 8.90, 9.00, 9.05, 9.20, 9.50, 9.65, 9.90, 10.10, 10.40, 10.55, 11.15, 11.55, 11.65, 12.05, 12.55, 13.05, 13.15, 13.55, 14.05, 14.55, 15.05, 15.55, 16.55
	Diameter (mm)	3.1, 4.0, 4.4, 4.5, 5.0, 5.5, 6.0
C- Type	**Total length (mm)**	7.9, 8.2, 8.35, 8.4, 8.7, 8.85, 9.4, 9.7, 9.85, 10.35, 11.35
	Diameter (mm)	3.9, 4.3, 5.5
Octa level Type	**Total length (mm)**	5.80
	Diameter (mm)	5.0, 5.5, 6.5

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

Zirconia Abutment	**titanium base**	**ZrGEN Abutment (Standard Type)**	**Minimum wall thickness (mm)**	0.4, 0.41, 0.43, 0.5, 0.55, 0.8, 1.05, 1.18
			Maximum angulation (°)	0
			Minimum gingival collar (ø)	2.2, 3.15, 3.25, 3.75, 4.25, 4.5
			Maximum gingival collar (ø)	3.1, 4.0, 4.4, 4.5, 5.0, 5.5, 6.0
			Minimum post height (mm)	1.2, 3.2, 4.7, 6.7
			Maximum post height (mm)	2.5, 4.5, 6.0, 8.0
		ZrGEN Abutment (C-Type)	**Minimum wall thickness (mm)**	0.12, 0.15,0.22, 0.32, 0.35, 0.42
			Maximum angulation (°)	0
			Minimum gingival collar (ø)	3, 3.4
			Maximum gingival collar (ø)	3.9, 4.3, 5.5
			Minimum post height (mm)	3.4
			Maximum post height (mm)	4.7
		ZrGEN Abutment (Octa level type)	**Minimum wall thickness (mm)**	0.75, 0.85, 1.35
			Maximum angulation (°)	0
			Minimum gingival collar (ø)	4.05, 4.5, 5.25
			Maximum gingival collar (ø)	5.0, 5.5, 6.5
			Minimum post height (mm)	3.7
			Maximum post height (mm)	5
	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 and Screw cleared under:

Type	**Dental Implant**				**Octa Abutment**		**Screw**	
	Name	**The widest diameter (mm)**	**Platform Diameter (mm)**	**510(k) Number**	**Connection Diameter (mm)**	**510(k) Number**	**510(k) Number**	**Model Name**
Standard Type	XPEED AnyRidge Internal Fixture	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	2.31, 2.8, 3.1, 3.3	K122231, K123870, K140091	-	-	K110955	AANMSF
	AnyOne Internal Fixture	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3		K123988	-	-	K123988	AS20
	MINi Internal Fixture	3.0, 3.4		K150537	-	-	K150537	MIAS14
	AnyRidge Octa 1 Fixture	3.6, 4.0, 4.4, 4.7, 4.8, 5.0,5.5		K182448	-	-	K182448	AROAS16B, AROAS16
C-Type	XPEED AnyRidge Internal Fixture	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4		K122231, K123870, K140091	-	-	K110955	AANMSF
	AnyOne Internal Fixture	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3		K123988	-	-	K123988	AS20
	AnyRidge Octa 1 Fixture	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5		K182448	-	-	K182448	AROAS16B, AROAS16
Octa Level Type	XPEED AnyRidge Internal Fixture	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	3.8, 4.0, 4.8, 5.0, 5.8, 6.0	K122231, K123870, K140091	4.0, 5.0, 6.0	K110955	K123988	IRCS200
	AnyOne Internal Fixture	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, ,6.8, 7.3, 7.8, 8.3		K123988	3.8, 4.8, 5.8	K123988		
	AnyRidge Octa 1 Fixture	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5		K182448	4.0, 5.0, 6.0	K182448		

The Scan Healing Abutment designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis. And they have the added design feature to be scannable an intraoral impression by digital scanner. The Scan Healing Abutment is provided with abutment screw and is provided gamma-sterile.

A groove is added to the top part to check the diameter, and to the connection part to check the correct connection with the fixture. And notches are added to check height (area excluding the length of the connection area from the total length). The detail information of groove and notch is below.

Diameter (Ø, mm)		4.2	4.7	5.7
Groove		0	1	2
Height (mm)	**AnyRidge**	6.9	7.9	9.9
	AnyOne	6.7	7.7	9.7
	AnyRidge Octa 1	7.35, 8.85	8.35, 9.85	10.35, 11.85
Notch		0	1	2
Anodizing		Gold	NA	Green

The dimensions of scan Healing Abutment are follows:

Total length (mm)	6.9, 6.7, 7.35, 7.7, 7.9, 8.35, 8.85, 9.79.85, 9.9, 10.35, 11.85
Diameter (mm)	4.2, 4.7, 5.7, 6.7

The Scan Healing Abutment is compatible with following MEGAGEN Implants and Screw cleared under:

Compatibility Fixture				**Compatibility Screw**
Compatible Implant System	**Device Name**	**510(k) Number**	**The widest Diameter (mm)**	**Model Name**
Xpeed AnyRidge Internal Implant System	Xpeed AnyRidge Internal Fixture	K122231 K123870 K140091	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	ARIHS1804, ARIHS1805, ARIHS1807
AnyOne	AnyOne	K123988	3.9, 4.3, 4.8, 5.3, 5.8,	AOIHS2004, AOIHS2005,
Internal Implant System	Internal Fixture		6.3, 6.8, 7.3, 7.8, 8.3	AOIHS2007
AnyRidge Octa 1 Implant	AnyRide Octa 1	K182448	3.6, 3.7, 4.0, 4.1, 4.4,	AROHS1604, AROHS1605,
System	Fixture		4.8, 5.0, 5.5	AROHS1607

6. Indication for use

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.

7. Basis for Substantial Equivalence

7.1. Comparison of the Indications for Use

<table>
<tr><th colspan="2">Table of Substantial Equivalence – Indications for Use</th></tr>
<tr><th>Subject Device</th><th>Indications for Use</th></tr>
<tr><td>MegaGen Co., Ltd.</td><td>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.</td></tr>
<tr><th>Predicate Device</th><th>Indications for Use</th></tr>
<tr><td>Medentika GmbH

Medentika CAD/CAM Abutments

K150203</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.24, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>

Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td></tr>
<tr><th>Reference Device</th><th>Indications for Use</th></tr>
<tr><td>MegaGen Co., Ltd

XPEED AnyRidge Internal Implant System

K122231</td><td>The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown,bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a 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.</td></tr>
<tr><td>MegaGen Co., Ltd

AnyOne Internal Implant System

K123988</td><td>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 06.0 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.</td></tr>
<tr><td>MegaGen Co., Ltd

MiNi Internal Implant System

K150537</td><td>The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:
- The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.</td></tr>
<tr><td>MegaGen Co., Ltd

AnyRidge Internal System

K110955</td><td>The AnyRidge Internal Implant System is intended to be surgically 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 Ø6.00mm) are dedicated for immediate 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.</td></tr>
<tr><td>Dentium Co., Ltd.

Dentium Ti-Base

K171622</td><td>Dentium Ti-Base abutments are intended for use on Dentium endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. All digitally designed abutments for use with Dentium Ti-Base abutments are intended to be sent to a Dentium-validated milling center for manufacture.</td></tr>
</table>

Biomet 3i BellaTek Encode Healing Abutments K173374	The TSV BellaTek Encode Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.

Substantial Equivalence Discussion

1. Similarities

The indications for use statement of the subject device has the same intended use as the primary predicate device, K150203, to support prosthetic rehabilitation when used with dental implants in the maxilla or mandible to treat partially or fully edentulous patients. Both the subject device and predicate device are intended for the digitally designed abutments to be manufactured at validated milling centers owned by each applicant.

2. Differences

The indications for use statement of the subject device is nearly identical to the primary predicate, except for minor changes in wording that do not affect the intended use. Different validated milling centers owned by each applicant are also referenced.

3. Discussion

The differences in the indications for use statement between the subject device and primary predicate device, K150203, are only minor changes in wording and do not affect the intended use for demonstrating substantial equivalence.

Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

7.2 Comparison for each component

7.2.1 TiGEN Abutment

	Subject Device	Predicate Device	Reference Devices			
510(k) Number	K220562	K150203	K122231	K123988	K150537	K182448
Device Name	TiGEN Abutment	Medentika CAD/CAM Abutments	XPEED AnyRidge Internal Implant System	AnyOne Internal Implant System	MiNi Internal Implant System	Ota Abutment For AnyRidge Octa 1 Implant System
Manufacturer	MegaGen Co., Ltd.	Medentika GmbH	MegaGen Co., Ltd.	MegaGen Co., Ltd.	MegaGen Co., Ltd.	MegaGen Co., Ltd.
Abutment Design	CAD/CAM Blank	CAD/CAM Blank	Multiple Designs	Multiple Designs	Multiple Designs	Multiple Designs
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment Angle	Up to 30°	Up to 30°	15°, 25°	15°, 25°	15°	0°
Abutment/ Implant Interface	Internal, External	Internal, External	Internal	Internal	Internal	Internal
Abutment Material	Ti-6Al-4V ELI	Titanium Alloy	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile; intended for terminal sterilization via autoclave
Abutment Diameter (mm)	10, 12	3.0~7.0	4.0~10.0	3.8~10.0	3.0~3.5	3.8
Octa abutment Interface Abutment	TiGEN Abutment (Octa level), is used with Octa Abutment. 	Unknown	Gold Cylinder Plastic Cylinder and CCM Cylinder, EZ Post Cylinder are used with Octa Abutment. 	Gold Cylinder Plastic Cylinder and CCM Cylinder, EZ Post Cylinder are used with Octa Abutment. 	NA	Gold Cylinder Plastic Cylinder and CCM Cylinder, EZ Post Cylinder are used with Octa Abutment. 
Platform Diameter (mm)	-Standard Type : 2.31, 2.8, 3.1, 3.3 -Octa Level Type : 3.8, 4.0, 4.8, 5.0, 5.8, 6.0	Unknown	3.1	3.1, 3.3	2.31	2.8, 3.3

<table>
<tr>
<td>Fixture Diameter (mm)</td>
<td>
<table>
<tr><td colspan="2">Standard Type</td></tr>
<tr><td>XPEED AnyRidge Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0</td></tr>
<tr><td>AnyOne Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0</td></tr>
<tr><td>MiNi Internal Implant System</td><td>3.0, 3.25</td></tr>
<tr><td>AnyRidge Octa 1 Implant System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr>
<tr><td colspan="2">Octa Level Type</td></tr>
<tr><td>XPEED AnyRidge Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0</td></tr>
<tr><td>AnyOne Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0</td></tr>
<tr><td>AnyRidge Octa 1 Implant System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr>
</table>
</td>
<td>3.3~7.0</td>
<td>Internal type:
4.0, 4.4, 4.9, 5.4, 5.9
(For normal ridge)
6.4, 6.9, 7.4, 7.9, 8.4
(For low ridge)</td>
<td>Internal type:
3.9, 4.3, 4.8, 5.3, 6.3, 7.3
(For normal ridge)
4.8, 5.8, 6.8, 7.8, 8.3
(For deep Thread)
4.8, 5.3, 6.3, 7.3
(For special length)</td>
<td>Internal Type;
3.0, 3.4</td>
<td>3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5</td>
</tr>
</table>

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device, K150203.

- Indications for use, Abutment Design, Restoration, Abutment Angle, Abutment/Implant Interface and Abutment Material.

The sterilization method is the same as the reference device, K182448.

2. Difference

The subject device has the different characteristic for the Octa Abutment Interface.

- It is unknown if K150203 has not Octa Level Abutment. Octa Level Abutment is identical with K122231 and K123988 that they are fastened on Octa Abutment.

3. Discussion

The subject device and primary predicate device are cylindrical titanium abutments with precision implant / abutment interface for use in fabricating a patient-specific abutment at a manufacturer-validated milling center.

The subject device and predicate device have common as following: Indications for use, Abutment Design, Restoration, Abutment Angle, Abutment/Implant Interface, Abutment Material and Abutment angle.

For the Abutment angle of subject devices, the worst case was selected for each Standard Type and Octa Level Type and fatigue tests were performed to confirm the substantial equivalence in accordance with 'ISO 14801' and 'Class II Special Controls Guidance Document: Root form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The test result supports that the subject device is substantially equivalent to the predicate device and the difference is not affecting the substantial equivalence.

The subject device and reference device, K122231 and K123988, have common as following: Octa Abutment Interface.

The subject device is 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). The steam sterilization validation of non-sterile subject device can be leveraged with reference device which was evaluated under the previous 510(k) submission, K182448.

Based on the information based in submission, it is concluded that the subject device is substantially equivalent to the predicate device.

7.2.2 ZrGEN Abutment

	Subject Device	Predicate Device	Reference Devices			
510(k) Number	K220562	K150203	K171622	K122231	K123988	K150537
Device Name	ZrGEN Abutment	Medentika CAD/CAM Abutments	Dentium Ti-Base	XPEED AnyRidge Internal Implant System	AnyOne Internal Implant System	MiNi Internal Implant System
Manufacturer	MegaGen Co., Ltd.	Medentika GmbH	Dentium Co., Ltd.	MegaGen Co., Ltd.	MegaGen Co., Ltd.	MegaGen Co., Ltd.
Abutment Design	TiBase	TiBase	TiBase	Multiple Designs	Multiple Designs	Multiple Designs
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment Angle	0°	Up to 30°	Up to 30°	15°, 25°	15°, 25°	15°
Prosthesis Attachment	Cement-retained Screw-retationed	Cement-retained	Cement-retained Screw-retationed	Cement-retained Screw-retationed	Cement-retained Screw-retationed	Cement-retained Screw-retationed
Abutment/ Implant Interface	Internal, External	Internal, External	Internal	Internal	Internal	Internal
Top-half Material	Zirconia ISO 13356	unknown	Zirconia ISO 13356	Zirconia ISO 13356	Zirconia ISO 13356	Zirconia ISO 13356
Range of Top-half Design Parameter (mm)	Diameter: Min 8.0 Gingival Collar Height: Min 2.0 Post Height: Min 7.0	unknown	unknown	Diameter: Min 8.0 Gingival Collar Height: Min 2.0 Post Height: Min 7.0	Diameter: Min 8.0 Gingival Collar Height: Min 2.0 Post Height: Min 7.0	NA
Abutment Material	Ti-6Al-4V ELI	Titanium Alloy	Unalloyed Titanium ASTM F67	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile	Non-sterile	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile; intended for terminal sterilization via autoclave	Non-sterile; intended for terminal sterilization via autoclave
Abutment Diameter (mm)	10, 12	3.0~7.0	Unknown	3.8~10.0	3.0~3.5	3.8
Octa Abutment Interface Abutment	ZrGEN Abutment (Octa level) and Zirconia top-half is used with Octa Abutment 	Unknown	Unknown	Gold Cylinder Plastic Cylinder and CCM Cylinder, EZ Post Cylinder are used with Octa Abutment. 	Gold Cylinder Plastic Cylinder and CCM Cylinder, EZ Post Cylinder are used with Octa Abutment. 	NA
Platform Diameter (mm)	-Standard Type, C-Type : 2.31, 2.8, 3.1, 3.3 -Octa Level Type : 3.8, 4.0, 4.8, 5.0, 5.8, 6.0	Unknown	3.6-7.0	3.1	3.1, 3.3	2.31
Fixture Diameter (mm)	Standard Type, C-Type XPEED AnyRidge Internal Implant System: 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0	3.3~7.0		Internal type: 4.0, 4.4, 4.9, 5.4, 5.9 (For normal ridge) 6.4, 6.9, 7.4, 7.9, 8.4 (For low ridge)	Internal type: 3.9, 4.3, 4.8, 5.3, 6.3, 7.3 (For normal ridge) 4.8, 5.8, 6.8, 7.8, 8.3 (For deep Thread) 4.8, 5.3, 6.3, 7.3	Internal Type; 3.0~3.5

	AnyOne Internal Implant System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0				(For special length)	
	MiNi Internal Implant System	3.0, 3.25					
	AnyRidge Octa 1 Implant System	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5					
	Octa Level Type						
	XPEED AnyRidge Internal Implant System	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0					
	AnyOne Internal Implant System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0					
	AnyRidge Octa 1 Implant System	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5					

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device, K150203.

- Indications for use, Abutment Design, Restoration, Abutment/Implant Interface, Abutment Material.

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device, K150203.

For Abutment Angle, the subject device is a straight type but predicate has angulation.

For Fop-half Material, Range of Top-half Design Parameter, Octa Abutment interface abutment. It can be covered by the reference device.

3. Discussion

The subject device and predicate device, K150203, are used for support of CAD/CAM fabricated zirconia superstructures.

The subject device and predicate device have common as following: Indications for use, Abutment Design, Restoration, Abutment/Implant Interface and Abutment Material. The ZrGEN Abutment and the top-half of ZrGEN Abutment is a straight type without angulation, so the fatigue testing is not considered.

Based on the information based in submission, it is concluded that the subject device is substantially equivalent to the predicate device.

7.2.3 Scan Healing Abutment

	Subject Device	Reference Device	
510(k) Number	K220562	K110955	K173374
Device Name	Scan Healing Abutment	Healing Abutment for AnyRidge Internal System	TSV™ BellaTek Encode Healing Abutment
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Biomet 3i
Appearance			
Diameter(mm)	4.2, 4.7, 5.7, 6.7	4.2, 5.2, 6.2, 7.2, 8.0, 10.0	3.5, 4.5, 5.7
Gingival height(mm)	3.8, 4.5, 4.8, 5.5, 6.5, 6.8	3.5, 4.5, 5.5, 6.5,7.5	3,5,7
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Shelf Life	5 years	5 years	5 years
Connection Interface	Internal Conical connection	Internal Conical connection	Internal
Surface treatment	Color Anodization	Machined	Machined
Principle of operation	The Scan Healing Abutment is used for non-submerged type surgery or for two-stage surgery. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. In a two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops. And it is a scannable that can help with the impression intraoral without removal.	The Healing Abutment is fastened into the female screw of dental implant and supports the gingival shaping.	The TSV™ BellaTek Encode Healing Abutment aids in prosthetic rehabilitation by supporting the surrounding gingival tissue during the healing period. The healing abutment is fixated on the implant using a retaining screw immediately after implant placement in a one-stage surgical protocol. And two-stage surgical protocol, the healing abutment is fixated on the implant following the bone healing period. The soft tissue is sutured around the healing abutment and the device remains in the mouth until the soft tissue fully develops. The occlusal surface of the device includes machined markings that provide information about the mating implant's position and orientation.
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device, K173374.

- Indications for use, Sterilization, Shelf Life, Connection, Surface treatment, Principle of operation and Material.

The sterilization method is the same as the reference device, K110955.

2. Differences

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

- Appearance

  The subject device is two-piece type so used with abutment screw. And upper could be used Scan Post with. But reference devices are one-piece type.

- Diameter and Gingival Height

  Diameter and gingival height of subject device lies within the dimension range of the reference devices.

3. Discussion

The Subject device and reference device have common in Indications for use, Sterilization, Connection, Surface treatment, Principle of operation and Material. And the differences are Appearance, Diameter and Gingival Height. But These do not affect device's performance and functionality.

The Sterilization validating testing has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10-6) under the previous 510(k) submission, K110955. 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 steam sterilization validation of non-sterile subject device can be leveraged with reference device, K110955.

Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

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.

Sterilization validation

The TiGEN Abutment and ZrGEN Abutment are supplied in non-sterile state. For TiGEN Abutment, sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 17665-1 and ISO 17665-2 to verify the sterility assurance level (10^{-6}) under the previous 510(k) submission, K182448. Therefore, it was leveraged from the prior cleared Abutment and Screw of K182448.

For ZrGEN Abutment, the steam sterilization validation of ZrGEN Abutment cemented Zirconia top-half has been carried out according to the protocol related to the requirements for validation described in ISO 17665-1 and ISO 17665-2.

The Scan Healing Abutment is supplied in sterile state. 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, K110955. 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 reference device, K110955.

Pyrogen and Endotoxin Test

The Scan Healing Abutment 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.

Biocompatibility

For TiGEN Abutment, 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" under the previous cleared K182448. As the TiGEN Abutment has same material and surface treatment as the FDA prior cleared, so it was leveraged from the prior cleared devices and the additional biocompatibility testing is not required.

For ZrGEN Abutment, the biocompatibility evaluation of ZrGEN Abutment construct 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". Cytotoxicity was performed according to ISO 10993-5 determining the subject device is non-cytotoxic.

For Scan Healing Abutment, 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" under the previous 510k(k) submission, K182448. As the Scan Healing abutment has same material and surface treatment as the FDA prior cleared, so it was leveraged from the prior cleared devices and the additional biocompatibility testing is not required.

Performance Test

Fatigue testing was performed on the worst-case TiGEN Abutment and compatible implant fixture constructs according to the requirements of ISO 14801:2016, Dentistry – Implants – Dynamic loading test for Endosseous Dental Implants.

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.

MR Compatibility

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

9. Summary of Clinical Testing

No clinical studies are submitted.

10. Conclusion

Based on the similarities, we conclude that the TIGEN Abutment, ZrGEN Abutment and Scan Healing Abutment are substantially equivalent to the predicate device.