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

September 18, 2024

Re: K234142
Trade/Device Name: TiGEN Abutment; PMMA 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: September 11, 2024
Received: September 13, 2024

Dear Hyo-Eun Lee:

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

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2026
See PRA Statement below.

510(k) Number *(if known)*
K234142

Device Name
TiGEN Abutment, PMMA Abutment and Scan Healing Abutment

Indications for Use *(Describe)*
The TiGEN Abutment, PMMA 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.

The PMMA Abutment is indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must be placed out of occlusion and are for temporary use (3 months).

For TiGEN Abutment and PMMA Abutment, all digitally designed abutments for use with PMMA Abutment and TiGEN 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

K234142

Spetember 17, 2024

1. Applicant / Submitter

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

2. Submission Correspondent

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

3. Device

- Trade Name: TiGEN Abutment, PMMA Abutment and Scan Healing Abutment
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Endosseous Dental Implant Abutment
- Primary Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3630

4. Predicate Device

- **Primary Predicate Device:**
  K220562 – TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment

- **Reference Device:**
  K150203 – Medentika CAD/CAN Abutments
  K220751 – Straumann BLX Temporary Abutment, VITA CAD-Temp, PMMA
  K122192 - Straumann Temporary Abutments VITA CAD-Temp
  K203554 - AnyOne External Implant System
  K210161 - AnyOne Onestage Implant System
  K230618 - MegaGen Dental Implant Systems Portfolio – MR Conditional
  K233208 - NobelProcera® Titanium ASC Abutment, Omnigrip Clinical Screw Titanium

5. Description

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

System	Type	Minimum wall thickness (mm)	Maximum angulation (°)	Minimum gingival collar height (mm)	Maximum gingival collar height (mm)	Minimum gingival collar (ø)	Maximum gingival collar (ø)	Minimum post height (mm)	Maximum post height (mm)
AR	**Holder**	0.67	30	2	5	4	11.5	4	6
AO	**Holder**	0.7			5	4.5			
MN	**Holder**	0.5			5	3.5			
BD	**Holder**	0.71			5	4			
	Holder Bridge	0.46			5	4			
AOO	**Holder**	0.05			3	4.8			
AOE	**Holder**	0.3			5	4			

The post height is defined as the cementable height of the abutment.

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

Compatibility Fixture				Compatibility Screw	
Compatible Implant System	**Product Name**	**510(k) Number**	**The widest Diameter (mm)**	**Product Name**	**510(k) Number**
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	Multi Post Screw	K122231, K123870, K140091, K110955
AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3	Abutment Screw	K182448
BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5	Abutment Screw	K123988
AnyOne External Implant System	AnyOne External Fixture	K052369, K203554	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8	Abutment Screw	K052369, K203554
AnyOn Onestage Implant System	AnyOn Onestage Fixture	K210161	3.9, 4.3, 4.8, 5.3	Multi Post Screw, Abutment Screw	K210161
MINi Internal Implant System	MINi Internal Fixture	K150537	3.0, 3.4	Abutment Screw	K150537

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

*Deciding When to Submit a 510(k) for a Change to an Existing Device / Guidance for Industry and Food and Drug Administration Staff / Document issued on October 25, 2017.

- **PMMA Abutment**

The PMMA Abutment is a temporary prosthesis used until the final prosthesis is placed for up to three months. The PMMA Post is machined with the temporary prosthetic in accordance with the intraoral structure by using dental CAD/CAM technology.

The PMMA Cuff is made of Ti-6Al-4V ELI alloy and available in various gingival heights. The PMMA Post is made of Polymethyl methacrylate and available in various diameters and lengths so that it can be used according to individual patient conditions.

All PMMA Abutment is provided non-sterile with abutment screw. The milled PMMA Abutment must be sterilized by users prior to use.

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

System	Part being milled						Manufactured part (Not be milled)		Maximum height (A+B, mm)
	Wall thickness (mm)	Maximum angulation (°)	Minimum Post diameter (ø, mm)	Maximum Post diameter (ø, mm)	Minimum post height (mm)	Maximum post height (A, mm)	Gingival collar Height (B, mm)	Gingival collar (ø, mm)	
AR	0.5	30	4.5	16	5.5	10.6	0.4, 1.3, 2.8	3.6, 3.7	11
BD								3.1, 3.2, 3.4, 3.5, 3.6, 3.7	
AO								3.5, 3.7	

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

Compatibility Fixture				Compatibility Screw	
Compatible Implant System	Product Name	510(k) Number	The widest Diameter (mm)	Product Name	510(k) Number
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	Multi Post Screw	K122231, K123870, K140091, K110955
AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3	Abutment Screw	K182448
BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5	Abutment Screw	K123988

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

*Deciding When to Submit a 510(k) for a Change to an Existing Device / Guidance for Industry and Food and Drug Administration Staff / Document issued on October 25, 2017.

- **Scan Healing Abutment**

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.

The dimensions of scan Healing Abutment are follows:

Device	Component
Scan Healing Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.2, 4.7, 5.7, 6.7 x 6.9, 7.9, 9.9, 11.9 mm **BLUEDIAMOND IMPLANT System** Ø 4.2, 4.7, 5.7, 6.7 x 12.35, 13.85 mm **AnyOne Inernal Implant System** Ø 4.2, 4.7, 5.7, 6.7 x 11.7 mm

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

Compatibility Fixture				Compatibility Screw	
Compatible Implant System	Product Name	510(k) Number	The widest Diameter (mm)	Product Name	510(k) Number
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	S.H.A Screw	Subject Device
AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3		
BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5		

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

*Deciding When to Submit a 510(k) for a Change to an Existing Device / Guidance for Industry and Food and Drug Administration Staff / Document issued on October 25, 2017.

6. Indication for use

The TiGEN Abutment, PMMA 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.
The PMMA Abutment is indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must be placed out of occlusion and are for temporary use (3 months).

For TiGEN Abutment and PMMA Abutment, all digitally designed abutments for use with PMMA Abutment and TiGEN 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><td>Subject Device
(K234142)</td><td>Indications for Use</td></tr>
<tr><td>MegaGen Co., Ltd.</td><td>The TiGEN Abutment, PMMA 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.
The PMMA Abutment is indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must be placed out of occlusion and are for temporary use (3 months).

For TiGEN Abutment and PMMA Abutment, all digitally designed abutments for use with PMMA Abutment and TiGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture.</td></tr>
<tr><td>Predicate Device
(K220562)</td><td>Indications for Use</td></tr>
<tr><td>MegaGen Co., Ltd.

TiGEN Abutment, ZrGEN Abutment and Scan Healing abutment</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><td>Reference Device</td><td>Indications for Use</td></tr>
<tr><td>Medentika GmbH

MedentikaCAD/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><td>Institut Straumann AG

Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA
(K220751)</td><td>Straumann® temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize, and shape the soft tissue during the healing phase. They must not be placed in occlusion. Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.</td></tr>
<tr><td>Straumann USA, LLC

Straumann Temporary Abutments VITA CAD-Temp
(K122192)</td><td>Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.</td></tr>
<tr><td>MegaGen Co., Ltd.

AnyOne External Implant System
(K203554)</td><td>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.</td></tr>
<tr><td>MegaGen Co., Ltd.

AnyOne Onestage Implant System
(K210161)</td><td>The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.</td></tr>
<tr><td colspan="2">Substantial Equivalence Discussion</td></tr>
<tr><td colspan="2">1. Similarities</td></tr>
</table>

The indications for use statement of the subject device has the same intended use as the primary predicate device, K220562, 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. For PMMA Abutment are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase additionally. This is the same intended use as the reference device, K220751.

3. Discussion

The differences in the indications for use statement between the subject device, primary predicate device(K220562) and reference device(K220751), are only minor changes in wording and do not affect the intended use for demonstrating substantial equivalence.

7.2. Comparison for each component

7.2.1. TiGEN Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th>Reference Device</th></tr>
<tr><td>510(k) Number</td><td>K234142</td><td>K220562</td><td>K150203</td></tr>
<tr><td>Device Name</td><td>TiGEN Abutment</td><td>TiGEN Abutment</td><td>Medentika CAD/CAM Abutments</td></tr>
<tr><td>Manufacturer</td><td>MegaGen Co., Ltd.</td><td>MegaGen Co., Ltd.</td><td>Medentika GmbH</td></tr>
<tr><td>Appearance</td><td> </td><td> </td><td>Unknown</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI</td><td>Ti-6Al-4V ELI</td><td>Titanium Alloy</td></tr>
<tr><td>Compatibility</td><td>XPEED AnyRidge Internal Implant System
BLUEDIAMOND IMPLANT System
AnyOne Internal Implant System
AnyOne External Implant System
AnyOne Onestage Implant System
MiNi Internal Implant System</td><td>XPEED AnyRidge Internal Implant System
BLUEDIAMOND IMPLANT System
AnyOne Internal Implant System
MiNi Internal Implant System</td><td>Unknown</td></tr>
<tr><td>Implant Diameter (mm)</td><td>
<table>
<tr><td>Xpeed AnyRidge Internal Implant System</td><td>4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4</td></tr>
<tr><td>BLUEDIAMOND IMPLANT System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr>
<tr><td>AnyOne Internal Implant System</td><td>3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3</td></tr>
<tr><td>AnyOne External Implant System</td><td>3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8</td></tr>
<tr><td>AnyOn Onestage Implant System</td><td>3.9, 4.3, 4.8, 5.3</td></tr>
<tr><td>MINi Internal Implant System</td><td>3.0, 3.4</td></tr>
</table>
</td><td>
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<tr><td>Xpeed AnyRidge Internal Implant System</td><td>4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4</td></tr>
<tr><td>BLUEDIAMOND IMPLANT System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr>
<tr><td>AnyOne Internal Implant System</td><td>3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3</td></tr>
<tr><td>MINI Internal Implant System</td><td>3.0, 3.4</td></tr>
</table>
</td><td>
<table>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</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></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.24, 4.0, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td></tr>
<tr><td>Straumann Bone Level</td><td>L</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></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</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></tr>
</table>
</td></tr>
<tr><td>CAD/CAM design parameters</td><td>
<table>
<tr><th>System</th><th>Type</th><th>Minimum wall thickness (mm)</th><th>Maximum angulation (°)</th><th>Minimum gingival collar height (mm)</th><th>Maximum gingival collar height (mm)</th><th>Minimum gingival collar (ø)</th><th>Maximum gingival collar (ø)</th><th>Minimum post height (mm)</th><th>Maximum post height (mm)</th></tr>
<tr><td>AR</td><td>Holder</td><td>0.67</td><td rowspan="8">30</td><td rowspan="8">2</td><td>5</td><td>4</td><td rowspan="8">11.5</td><td rowspan="8">4</td><td rowspan="8">6</td></tr>
<tr><td>AO</td><td>Holder</td><td>0.7</td><td>5</td><td>4.5</td></tr>
<tr><td>MN</td><td>Holder</td><td>0.5</td><td>5</td><td>3.5</td></tr>
<tr><td rowspan="2">BD</td><td>Holder</td><td>0.71</td><td>5</td><td>4</td></tr>
<tr><td>Holder Bridge</td><td>0.46</td><td>5</td><td>4</td></tr>
<tr><td>AOO</td><td>Holder</td><td>0.05</td><td>3</td><td>4.8</td></tr>
<tr><td>AOE</td><td>Holder</td><td>0.3</td><td>5</td><td>4</td></tr>
</table>
AR: XPEED AnyRidge Internal System
AO: AnyOne Internal Implant System
MN: MiNi Internal Implant System
BD: BLUEDIAMOND IMPLANT System
AOO: AnyOne Onestage Implant System
AOE: AnyOne External Implant System
</td><td>
<table>
<tr><td rowspan="9">Standard Type</td><td>Minimum wall thickness (mm)</td><td>0.47</td></tr>
<tr><td>Maximum angulation (°)</td><td>30</td></tr>
<tr><td>Minimum gingival collar height (mm)</td><td>2.00</td></tr>
<tr><td>Maximum gingival collar height (mm)</td><td>5.00</td></tr>
<tr><td>Minimum gingival collar (ø)</td><td>3.50, 4.00, 4.50</td></tr>
<tr><td>Maximum gingival collar (ø)</td><td>9.50, 11.50</td></tr>
<tr><td>Minimum post height (mm)</td><td>4.00</td></tr>
<tr><td>Maximum post height (mm)</td><td>6.00, 6.50</td></tr>
<tr><td rowspan="7">Octa level Type</td><td>Minimum wall thickness (mm)</td><td>0.47</td></tr>
<tr><td>Maximum angulation (°)</td><td>30</td></tr>
<tr><td>Minimum gingival collar (ø)</td><td>4.00</td></tr>
<tr><td>Maximum gingival collar (ø)</td><td>9.50, 11.50</td></tr>
<tr><td>Minimum post height (mm)</td><td>4.00</td></tr>
<tr><td>Maximum post height (mm)</td><td>6.00</td></tr>
</table>
</td><td>Unknown</td></tr>
<tr><td>Sterilization Method</td><td>Non-sterile
(Steam sterilized before use)</td><td>Non-sterile
(Steam sterilized before use)</td><td>Non-sterile
(Steam sterilized before use)</td></tr>
</table>

Substantial Equivalence Discussion

1. Similarities

- Material: subject device and predicate device have the same material.
- Sterilization Method: Both the subject device and the predicate device are provided as non-sterile and must be sterilized by the user before use.
- Diameter: : subject device and predicate device have the same diameter.

2.Difference

- Compatibility and Implant diameter: For the subject device, TiGEN Abutment of AnyOne External Implant and AnyOne Onestage Implant System was added. However, this system has already been clear to the FDA before with K052369, K203554 and K210161, and the TiGEN Abutment for each system has been tested to confirm the performance.
- Total length: Although shorter length is added, it can provide users with a wider range of dimensions.
- CAD/CAM design parameters: It has different parameter for each implant system.

3. Discussion

The subject device and predicate device are used with each compatible implant with MegaGen products has already been proven through performance tests. The length of subject device is different. The length may vary depending on the shape of the holder part connected to the milling machine. However, safety of subject device was confirmed through fatigue testing considering the worst-case when the user manufactures and uses it according to CAD/CAM design parameters, and it can be said to be substantially the same as previously cleared K052369, K203554 and K210161.

7.2.2. PMMA Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th colspan="3">Reference Device</th></tr>
<tr><td>510(k) Number</td><td>K234142</td><td>K220562</td><td>K233208</td><td>K220751</td><td>K122192</td></tr>
<tr><td>Device Name</td><td>PMMA Abutment</td><td>TiGEN Abutment</td><td>NobelProcera Titanium ASC Abutment</td><td>Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA</td><td>Straumann Temporary Abutments VITA CAD-Temp</td></tr>
<tr><td>Manufacturer</td><td>MegaGen Co., Ltd.</td><td>MegaGen Co., Ltd.</td><td>Nobel Biocare AB</td><td>Institut Straumann AG</td><td>Straumann USA, LLC</td></tr>
<tr><td>Appearance</td><td> </td><td> </td><td>Unknown</td><td> </td><td>Unknown</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI, PMMA</td><td>Ti-6Al-4V ELI</td><td>Titanium aluminum vanadium alloy
Ti6Al4V ELI (ISO 5832-3, ASTM F136)
MTA005</td><td>Titanium alloy/TAN (Ti-6Al-7Nb), PMMA</td><td>Titanium alloy/TAN (Ti-6Al-7Nb), PMMA</td></tr>
<tr><td>Compatibility</td><td>XPEED AnyRidge Internal Implant System
BLUEDIAMOND IMPLANT System
AnyOne Internal Implant System</td><td>XPEED AnyRidge Internal Implant System
BLUEDIAMOND IMPLANT System
AnyOne Internal Implant System
MiNi Internal Implant System</td><td>Conical connection: NP, RP, WP
Tri Channel Connection: NP, RP, WP, 6.0
TCC: N/A</td><td>RB/WB and WB</td><td>Narrow CrossFit® (NC)
Regular CrossFit® (RC)
Narrow Neck CrossFit® (NNC)
Regular Neck (RN)
Wide Neck (WN)</td></tr>
<tr><td>Implant Diameter (mm)</td><td>Xpeed AnyRidge Internal Implant System: 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
BLUEDIAMOND IMPLANT System: 3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5
AnyOne Internal Implant System: 3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3</td><td>Xpeed AnyRidge Internal Implant System: 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
BLUEDIAMOND IMPLANT System: 3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5
AnyOne Internal Implant System: 3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
MINi Internal Implant System: 3.0, 3.4</td><td>Unknown</td><td>Unknown</td><td>Unknown</td></tr>
<tr><td>CAD/CAM design parameters</td><td>System: AR, BD, AO
Part being milled: Wall thickness (mm): 0.5; Maximum angulation (°): 30; Minimum Post diameter (ø, mm): 4.5; Maximum Post diameter (ø, mm): 16; Minimum post height (mm): 5.5; Maximum post height (A, mm): 10.6
Manufactured part (Not be milled): Gingival collar Height (B, mm): 0.4, 1.3, 2.8; Gingival collar (ø, mm): AR: 3.6, 3.7; BD: 3.1, 3.2, 3.4, 3.5, 3.6, 3.7; AO: 3.5, 3.7
Maximum height (A+B, mm): 11
AR: XPEED AnyRidge Internal System
AO: AnyOne Internal Implant System
BD: BLUEDIAMOND IMPLANT System</td><td>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</td><td>Minimum gingival height: 0.3mm
Minimum post height: (length above the abutment collar / gingival height): 4mm</td><td>Unknown</td><td>Unknown</td></tr>
<tr><td>Prosthesis Fixation</td><td>Screw-retained</td><td>Screw-retained</td><td>Mechanical screw connection</td><td>Screw-retained</td><td>Screw-retained</td></tr>
<tr><td>Sterilization Method</td><td>Non-sterile</td><td>Non-sterile</td><td>Non-sterile</td><td>Non-sterile</td><td>Non-sterile</td></tr>
<tr><td>Duration of Use</td><td>3 months</td><td>NA</td><td>Unknown</td><td>6 months</td><td>6 months</td></tr>
<tr><th colspan="6">Substantial Equivalence Discussion</th></tr>
<tr><td colspan="6">1. Similarities
- Compatibility and Implant Diameter: subject device and predicate device have the same compatible implant system.
- Prosthesis Fixation: Both the subject device and the predicate device are fixed to the fixture with screws.
- Sterilization Method: Both the subject device and the predicate device are provided as non-sterile and must be sterilized by the user before use.</td></tr>
</table>

2.Difference

- Abutment Diameter, Overall abutment length and CAD/CAM design parameters: Both the subject device and the predicate device have a difference in diameter before milling. However, it can be used as a milled crown such as a reference device (K220751). It can only be machined with allowable ranges of design parameters after CAD/CAM patient-matching provided by the manufacturer.
- Total length: the Dimensions of subject device are slightly different with predicate and reference devices. But the variety of the size can be possible to operate more precise treatment to meet each patient's condition.
- Duration of Use: Since the subject device is a temporary prosthesis, we recommend using it for 3 months in the mouth of the actual patient.
- CAD/CAM design parameters: It has different parameter for each implant system.

3. Discussion

The subject device and predicate device are used with each compatible implant with MegaGen and Straumann and compatibility with MegaGen products has already been proven through performance tests.

The dimensions of subject device and predicate device are differnce but the length of PMMA Post is nearly identical to predicate devices. Since each system has a different connection structure, the majority of the Diameter and Overal abutment length are not same to the predicate and reference devices. This difference is to provide various diameters, lengths, and heights of prosthesis because the size and length of the alveolar bone hole vary which enables more appropriate treatment for the patient. So the difference is not affecting the substantial equivalence.

However, safety of subject device was confirmed through fatigue testing considering the worst-case when the user manufactures and uses it according to CAD/CAM design parameters.

Although the period of use is different from that of the predicate device, the suggested maximum period of use may be different as the subject device is a temporary abutment used before the final prosthesis is manufactured. In addition, since the expiration date of the subject device product has been verified, it does not affecting the equivalence of the predicate device.

7.2.3. Scan Healing Abutment

	Subject Device	Predicate Device
510(k) Number	K234142	K220562
Device Name	Scan Healing Abutment	Scan Healing Abutment
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Appearance		
Diameter(mm)	4.2, 4.7, 5.7, 6.7	4.2, 4.7, 5.7, 6.7
Length(mm)	6.9, 7.9, 9.9, 11.7, 12.35, 13.85	6.9, 6.7, 7.35, 7.7, 7.9, 8.35, 8.85, 9.79.85, 9.9, 10.35, 11.85
Sterilization	Gamma irradiation	Gamma irradiation
Shelf Life	5 years	5 years
Connection Interface	Internal Conical connection	Internal Conical connection
Surface treatment	Color Anodization	Color Anodization
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI

Substantial Equivalence Discussion

1. Similarities

- Diameter: Both the subject device and predicate device have the same diameter.
- Sterilization Method: Both the subject device and the predicate device are provided as sterile with gamma irradiation.
- Shelf life: Both the subject device and the predicate device have the same shelf life.
- Connection Interface: Both the subject device and predicate device have the same connection.
- Surface treatment: Both the subject device and predicate device are anodized.
- Material: subject device and predicate device have the same material.

2.Differences

- Length: the length dimensions of subject device are slightly different with predicate and reference devices. But the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

Only the length of subject device and predicate device are differnce. But this difference is to provide various dimension of prosthesis because the length of the alveolar bone hole vary which enables more appropriate treatment for the patient. The variety of the size and design can be possible to operate more precise treatment to meet each patient's condition. The subject device is intended for temporary use and design differences compared with predicate device are very minor so it does not affect device's fundamental functions and safety.

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.

Sterilization validation and Shelf life

The TiGEN Abutment and Abutment Screw are supplied in non-sterile state. 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). Validation Testing was conducted on a worst-case test article from our previously cleared device, K220562.

The PMMA Abutment is supplied in non-sterile state. Serilization 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). Accelerated shelf life study on PMMA Abutment was performed for five years in accordance with ASTM F1980-07.

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.

Performance test

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

- Fatigue test

MR Compatibility

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 TiGEN Abutment, PMMA Abutment and Scan Healing Abutment are substantially equivalent to the predicate device.