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

February 3, 2022

Re: K210826
Trade/Device Name: Healing Abutment, Cover Screw
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 28, 2021
Received: January 5, 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
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)*
K210826

Device Name
Healing Abutment, Cover Screw

Indications for Use *(Describe)*
MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.

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 K210826

Date: February 3, 2022

1. **Applicant / Submitter**

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2. **Submission Correspondent**

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3. **Device**

- Trade Name: Healing Abutment, Cover Screw
- 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:**

K192436 - Healing Abutments and Cover Screws

- **Reference Device:**

K110955 – AnyRidge Internal Implant System
K123988 – AnyOne™ Internal Implant System
K182448 – AnyRidge Octa 1 Implant System
K181138 - IS-III active System
K150537 – MiNi Internal Implant System

5. Description

The Healing Abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile before a final restoration is placed. The Scan Healing Abutment Screw is used to connect the Healing Abutment to the endosseous implant.

The Healing Abutments are several types depending on the anatomic location. There are Incisor Type, Canine Type, Molar Type, Special type suitable for the patient's oral environment.


Incisor type


Canine type


Molar type


Special type

The Healing Abutment and Scan Healing Abutment screw are 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	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
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5

The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement. It is used for submerged type surgery. It is sterilized using gamma irradiation during manufacturing process. It is single use devices.

The Cover Screw 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	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

The Healing Abutment, Scan Healing Abutment Screw and Cover Screw are consisted of the following devices.

Device		Content	
1. Abutment	**Healing Abutment**	Description	The Healing Abutment helps to form suitable emergence profile during period of gingival healing. There are five types of Healing Abutments, Incisor, Canine, Pre-molar, Molar and Special type.
		Material	Ti-6Al-4V ELI of ASTM F136-13
		Dimension (Diameter, Total Length)	Diameter: Ø 4.0 ~ 10.0 mm Total Length: 4.4 ~ 11.35 mm
		Angulation	Straight
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System
	Scan Healing Abutment Screw	Description	The Scan Healing Abutment Screw is used for connecting Healing Abutment to the endosseous implant.
		Used with	Healing Abutment
		Material	Ti-6Al-4V ELI of ASTM F136-13
		Dimension (Diameter & Total Length)	Ø1.95 x 7.8 ~ 12.8 mm Ø2.0 x 6.9 ~ 10.9 mm Ø2.1 x 8.0 ~ 13.0 mm
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System
2. Cover Screw		Description	The Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement. It is used for submerged type surgery.
		Material	Ti-6Al-4V ELI of ASTM F136-13
		Dimension (Diameter, Total Length)	Ø6.0 x 7.2 ~ 8.3 mm
		Angulation	Straight
		Compatible Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System

6. Indication for use

MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.

7. Basis for Substantial Equivalence

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

Healing Abutment

	Subject Device	Primary Predicate Device	Reference Device			
510k	K210826	K192436	K110955	K123988	K182448	K181138
Device Name	Healing Abutment	Healing Abutment	Healing Abutment for AnyRidge Internal Implant System	Healing Abutment for AnyOne Internal Implant System	Healing Abutment for AnyRidge Octa 1 Implant System	IS Encoded Healing Abutment for IS-III active System
Manufacturer	MegaGen Implant Co., Ltd.	Dentium Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Neobiotech Co., Ltd.
Design						
Diameter (Ø, mm)	4.0 ~ 10.0	3.70 ~ 9.64	4.2 ~ 10.0	4.2 ~ 9.7	3.2 ~ 7.2	4.0 ~ 9.0
Gingival Height (Cuff Height, mm)	2.0 ~ 7.0	unknown	3.5 ~ 9.5	2.3 ~ 8.8	2.5 ~ 9.5	2.3 ~ 7.3
Total Length (mm)	4.4 ~ 11.35	6.15 ~ 14.66	8.4 ~ 14.4	8.7 ~ 15.2	8.6 ~ 15.6	2.5 ~ 7.5
Use with Screw	Use with Screw	N/A	N/A	N/A	N/A	Use with Screw
Male Screw x Pitch (mm)	M1.8x0.35P, M2.0x0.40P, M1.6x0.35P	unknown	M1.8x0.35P	M2.0x0.4P	M1.6x0.35P	unknown
Connection	Internal Hex	Internal	Internal Conical connection	Internal Conical connection	Internal Conical connection	Internal Hex
Materials	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Surface Treatment	Machined (Abutment) Anodizing (Screw)	Machined	Machined	Machined	Anodizing	Machined
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	5 years	unknown	5 years	5 years	5 years	5 years

	Subject Device	Primary Predicate Device	Reference Device			
indication for use	MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	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 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 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches forthe 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.	The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the primary predicate device and prior cleared reference devices.
   - Design, Use with Screw, male Screw x Pitch, Connection, Materials, Surface Treatment, Sterilization, Shelf Life and Indication for use

2. **Differences**

   The subject device has the different characteristic for the followings compared to the primary predicate device and prior cleared reference devices.
   - Diameter, Gingival Height and Total Length

   The Dimensions of subject device are slightly different with predicate and reference devices, but they are lie within the range of predicate device. But it does not cause a matter in substantial equivalence since these size differences are very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. **Discussion**

   Some of Healing Abutments had been FDA cleared with K110955, K123988 and K182448 but this submission is being submitted to add new dimensions with five different types to the patient's oral environment in the compatible implant system. Therefore, the proposed Healing Abutment and all prior cleared devices have common in Indication for Design, Diameter, Total Length, Use with Screw, Male Screw x Pitch, Connection, Material, Surface Treatment, Sterilization, Shelf Life and Indication for use. The differences are explained not affecting on the substantial equivalence.

   Also, the fatigue testing is not considered since they help to form suitable emergence profile during period of gingival healing and are not placed into occlusion.

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

The Cover Screw 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 device slightly differ from the predicate device however it is very minor not affecting substantial equivalence.

Based on the comparison charts below provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

Cover Screw

	Subject Device	**Primary Predicate Device**	**Reference Device**		
510k	K210826	K192436	K110955	K123988	K150537
Device Name	Cover Screw	Cover Screw	Cover Screw for AnyRidge Internal Implant System	Cover Screw for AnyOne Internal Implant System	Cover Screw for MiNi Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	Dentium Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Design					
Diameter (Ø, mm)	6.0	3.10 ~ 4.30	3.5	3.5 ~ 4.1	2.6, 3.5
Total Length (mm)	7.2 ~ 8.3	4.70 ~ 8.92	5.7 ~ 7.5	6.75 ~ 8.75	3.1 ~ 10.25
Male Screw x Pitch (mm)	M1.8x0.35P, M2.0x0.40P	unknown	M1.8x0.35P	M2.0x0.40P	M1.4x0.30P, M1.6x0.35P, M1.8x0.35P, M2.0x0.40P
Materials	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Surface Treatment	Machined	TiN Coated	Anodizing	Anodizing	Anodizing, Machined
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	5 years	unknown	5 years	5 years	5 years

	Subject Device	Primary Predicate Device	Reference Device		
indication for use	MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	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 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 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 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.

Substantial Equivalence Discussion

1. Similarities

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

- Design, Male Screw x Pitch, Materials, Surface Treatment, Sterilization, Shelf Life and Indication for use

2. Differences

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

- Diameter

The Diameter of subject device is slightly different with predicate and reference devices. But it does not cause a matter in substantial equivalence since the difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Total Length

The Total Length of subject device are slightly different with predicate and reference devices, but they are lie within the range of predicate device. But it does not cause a matter in substantial equivalence since these size differences are very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

3. Discussion

The proposed Cover Screw had been FDA cleared under K110955, K123988 and K150537 but this submission is being submitted to add new dimensions in the compatible implant system. Therefore, the proposed Cover Screw and prior cleared devices have common in Indication for Design, Dimensions, Male Screw x Pitch, Materials, Surface Treatment, Sterilization, Shelf Life and Indication for use. The differences are explained not affecting on the substantial equivalence.

4. 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 additional biocompatibility testing is not required on the Healing Abutment and Cover Screw since these have same material composition, manufacturing process and patient contacting parts as the prior cleared Healing Abutment and Cover Screw for AnyRidge Internal Implant System(K110955), AnyOne Internal Implant System(K123988), AnyRidge Octa 1 Implant System(K182448) and MiNi Internal Implant System(K150537).

Modified Surface Treatment

The Healing Abutment is non surface-treated as predicate devices, IS Encoded Healing Abutment(K181138) and Healing Abutment for AnyRidge Internal Implant System(K110955), AnyOne Internal Implant System(K123988) and AnyRidge Octa 1 Implant System(K182448).

For Scan Healing Abutment Screw, the surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'.

The Scan Healing Abutment Screw has same surface treatment and manufacturing process as prior cleared device, AnyRidge Octa 1 Implant System (K182448) for Anodizing. The purpose of Anodizing for Scan Healing abutment Screw is to distinguish the sizes with the naked eyes for convenience. And It doesn't affect device's fundamental functions, safety and effectiveness.

Pyrogen and Endotoxin Test

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP 39 <85>.

Sterilization validation and Shelf Life

Sterilization validating testing has been performed in accordance with ISO 11137 to verify the sterility assurance level (10^{-6}). The tests to validate the Shelf Life of the device through the proposed Shelf Life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 5 years Shelf Life.

Also, the following guidance documents were referred to:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Performance test

The five types of Healing Abutment in each Implant System have similar design and same indication for use, principle of operation, technical characteristics and function. And since the connection dimensions of D1, the Healing Abutment and Implant of each implant system, are all the same, so it was not necessary to consider the worst-case scenario when selecting a sample for the performance test of the subject device such as the precision fit test. Therefore, the test was conducted by selecting randomly among the subject devices in each Implant System.

- Precision Fit Test

9. Summary of Clinical Testing

No clinical studies are submitted.

10. Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the Healing Abutment and Cover Screw is substantially equivalent to the predicate device as herein.