October 8, 2019

MegaGen Implant Co., Ltd.
JiYoung Son
Assistant Reserch Engineer
45, Secheon-ro, 7-gil, Dasa-eup, Dalesong-gun
Daegu
REPUBLIC OF KOREA

Re: K191127
Trade/Device Name: Advanced Intermezzo Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 20, 2019
Received: July 10, 2019

Dear JiYoung Son:

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,

for Srinivas Nandkumar
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191127

Device Name
Advanced Intermezzo Implant System

Indications for Use *(Describe)*

Advanced Intermezzo Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Advanced Intermezzo Implant System consists of single-stage, root-form dental implants.
The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Advanced Intermezzo Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.

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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V. 510(k) SUMMARY (K191127)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 08, 2019

1. Applicant / Submitter

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Tel: + 82-53-222-2828

2. Submission Correspondent

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3. Device

- Trade Name: Advanced Intermezzo Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: Class II, 21 CFR 872.3640

4. Predicate Device:

- Primary Predicate:
  K051018 Intermezzo Implant System

- Reference Devices:
  K112540 S-MiNi Implant
  K123870 XPEED AnyRidge Internal Implant System

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) Number	K191127	K051018	K112540	K123870
Device Name	Advanced Intermezzo Fixture	Intermezzo™ Implant Fixture	S-MiNi Implant	XPEED AnyRidge Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Neobiotech Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	Advanced Intermezzo Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Advanced Intermezzo Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Advanced Intermezzo Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.	Intermezzo™ Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Intermezzo™ Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Intermezzo™ Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.	The S-MiNi Implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.	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 Ø 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.
Appearance				
Material	CP Ti Grade 4	CP Ti Grade 3	CP Ti Grade 4	CP Ti Grade 4
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Diameter(Ø)	2.2/ 2.6/ 3.0 mm	1.8/ 2.2/ 2.5/ 3.1 mm	2.0 / 2.5/ 3.0/ 3.5 mm	Internal type 4.0, 4.4, 4.9, 5.4, 5.9mm (For normal ridge)

				6.4, 6.9, 7.4, 7.9, 8.4mm (For low ridge)
Length (mm)	7.0/ 8.5/ 10.0/ 11.5/ 13.0 mm	10.0/ 11.5/ 13.0/ 15.0 mm	7.0/8.5/10.0/11.5/13.0/15.0 mm	Internal type 7.7, 9.2, 10.7, 12.2, 14.20, 17.2mm (For normal ridge) 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)
Surface treatment	Sand-blasted, Large grit, Acid-etched (S.L.A)	RBM	RBM	Sand-blasted, Large grit, Acid-etched (S.L.A)
Implant-to-abutment connection	One-Piece Implant	One-Piece Implant	One-Piece Implant	Hex
Feature	Root-Form, Threaded	Root-Form, Threaded	Root-Form, Threaded	Tapered Form, Threaded
Sterilization	Sterile	Sterile	Sterile	Sterile
Principle of operation	This product is a root-type fixture which is inserted in the alveolar bone.	This product is a root-type fixture which is inserted in the alveolar bone.	This product is a root-type fixture which is inserted in the alveolar bone.	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Shelf Life	5 Years	5 Years	-	5 Years

Substantial Equivalence Discussion

The subject device has the same material, indication for use, and principle of operation as the predicate device.
The difference between the subject device and the predicate device is surface treatment and slight fixture design. The difference in surface treatment is covered by reference 2 and the difference in diameter and length is covered by reference 1.
In comparison with fixture design, the test result of fatigue test supported that the subject device is substantially equivalent to the predicate device.

Comfort Cap

	Subject Device	Predicate Device
510(k) Number	K191127	K051018
Device Name	**Comfort Cap** for Advanced Intermezzo System	**Intermezzo Protective Cap** for Intermezzo System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	Advanced Intermezzo Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Advanced Intermezzo Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Advanced Intermezzo Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.	Intermezzo™ Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Intermezzo™ Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Intermezzo™ Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.
Appearance		
Diameter	3.6 mm	3.2 mm
Length	9.0 mm	9.2 mm
Surface treatment	Injection molding	Injection molding
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	Straight	Straight
Material	POM	POM
Principle of operation	This product is a cap to prevent damage of tongue by the post area of fixture in oral cavity.	This product is a cap to prevent damage of tongue by the post area of fixture in oral cavity.
Substantial Equivalence Discussion		
The subject device has the same intended use, material, surface treatment, design, and principle of operation as the predicate device. The size range of the subject device is slightly different from the predicate devices.		

5. Description:

The Advanced Intermezzo Fixture is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method.

The system offers the following components.
- Comfort Cap

6. Indication for use:

Advanced Intermezzo Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function.
Advanced Intermezzo Implant System consists of single-stage, root-form dental implants.
The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Advanced Intermezzo Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.

7. Basis for Substantial Equivalence

Advanced Intermezzo Implant System is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design. There are slight differences in design, however, it is very minor not affecting substantial equivalence. We have performed the fatigue test, and the test result of fatigue test supported that the subject device is substantially equivalent to the predicate device.
Based on the information and test results provided in submission, we conclude that the subject device is substantially equivalent to the predicate devices.

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137 -1,2,3
- 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 year shelf life.
- The following tests were done to evaluate the fixtures that have SLA treatment:
  Surface Morphology by energy dispersive spectrometer (EDS), Surface Roughness Analysis, GC(Gas Chromatography)/LC (Liquid chromatography) Analysis, and IC Analysis.
- The fixture has the same material as the predicate device (K051018), the cap to protect abutment parts has the same material as the predicate device (K051018). The biocompatibility of the predicate final products was evaluated under the previous 510K submission.
- The endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL which was referenced from the USP 39 <85>.
- Comparative fatigue testing per ISO 14801 was conducted on the subject device and primary predicate

9. Conclusion

Based on the similarities, we conclude that the Advanced Intermezzo Implant System is substantially equivalent to the predicate devices.