510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

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Device Information:
Device Name: Xpeed AnyRidge Internal Implant System
Classification Name: Implant, Endosseous, Root-Form
Common Name: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Regulation number: 21 CFR 872.3640
Date Prepared: 3/24/2014

Device Description
The Xpeed AnyRidge Internal Implant System contains two types of fixtures, Normal ridge type and low ridge type. The fixtures are made from CP Ti Grade 4, and the surface treatment is done with S.L.A (Sand-blasted, Large grit, Acid-etched). The fixtures are used to replace missing teeth in various situations ranging from a single missing tooth to the completely edentulous individual. The wide ranges of size are provided to be in conformance with each patient, or to cover up in case of due to deficiency in implant operation. The fixture is used as two stages, root-form dental implants, associated with abutment systems, which provide the clinician with the screw and cement retained restoration for multi-mount options. This system has 4.0, 4.4, 4.9, 5.4, 5.9mm diameters for normal ridge and 6.4, 6.9, 7.4, 7.9, 8.4mm diameters for low ridge fixtures. In addition, this system has 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm lengths for normal ridge and 7.9, 9.4, 10.9, 12.4, 14.4mm lengths for low ridge fixtures.

The purpose of this submission is

- to modify the manufacturing process of the fixtures that was mistakenly documented under 510(k) number K122231.

Indication for use
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.

Predicate devices

- AnyRidge Internal Implant System (K110955)
- Straumann Anodized Neck Implants (K061176)

Substantial Equivalence Comparison

The Xpeed AnyRidge Internal Implant System has a substantially equivalent intended use as the identified predicate. The Xpeed AnyRidge Internal Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium. The subject and predicate device are same in size and materials. When compared with predicate device, no new questions of substantial equivalence have been raised for the Xpeed AnyRige Internal Implant System.

	Subject Device	**Predicate Device**	
510(k) Number	Not available yet	K110955	K061176
Device Name	Xpeed AnyRidge Internal Implant System	AnyRige Internal Implant System	Straumann Anodized Neck Implants
Manufacturer	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd	Straumann
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant
Design	Xpeed AnyRidge Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex	AnyRidge Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex	-Single-stage or two-stage - Single-tooth and/or multiple tooth applications -Neck diameter : 3.5mm, 4.8mm
Material	CP Ti Grade 4	CP Titanium, Gr.4 and Ti-6Al-4V, ELI	CP4 Titanium
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Fixture Diameter	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)	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)	3.3, 4.1, 4.8mm

Fixture Height	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)	Internal type 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm (For normal ridge) 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)	8, 10, 12, 14mm
Product Code	DZE, NHA	DZE	N/A
Surface treatment	SLA	SLA	N/A

Non-Clinical Test Data

Appearance, Dimension, Packaging, Extraction, and Sterility tests were performed to prove that the modification do not affect the substantial equivalence with the predicate device.

Appearance and Dimension test have been performed in accordance with the in-house standard and Packaging test has been performed in accordance with ISO 11607. Those tests have been performed to evaluate the substantial equivalence in size and packaging compared to the predicate device.

Extraction and sterility test have been performed in accordance with USP<711> and USP<71>.

Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate device.

The result of the above tests have met the criteria of the standard, and proved the substantial equivalence with the predicate device.

Non-clinical testing consisted of performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments."

Testing Item		References
Biocompatibility test	Acute systemic toxicity test	ISO 10993-11
	Sensitization test	ISO 10993-10
	Cytotoxicity	ISO 10993-5
	Intracutaneous reactivity test	ISO 10993-10
	Implantation test	ISO 10993-6
Surface analysis	XPS	In-house standard
	EPMA	In-house standard
	XRD	In-house standard
	ICP	In-house standard
	SEM	In-house standard
	Surface roughness	In-house standard

The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification concludes that the Xpeed AnyRidge Internal Implant system is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12,2014

MegaGen Implant Company, Limited
C/O Ms. Minkyung Hahm
Contact/US Agent
Kodent, Incorporated
325 North Puente Street, Unit B
Brea, California 92821

Re: K140091
Trade/Device Name: Xpeed AnyRidge Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 4, 2014
Received: November 4, 2014

Dear Ms. Hahm:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K140091

Device Name: Xpeed AnyRidge Internal Implant System

Indications for Use:

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.

Prescription Use _____X_____ AND/OR Over The-Counter Use_____
(Part 21 CFR 801 Sub part D) (21 CFR 807 Sub part C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)