

MAR 27 2013

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.

Submitter:

Dong Guk Ha
MegaGenImplant Co., Ltd.
472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si
Gyeongbuk, South Korea
Phone: 82-53-857-5770
Fax: 82-53-857-5432

Contact /US agent:

April Lee
KoDent, Inc.
325 N. Puente St. Unit B
Brea, CA 92821
Phone: 714-525-0114
Fax: 714-525-0116

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
Subsequent Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 12/12/2012

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 Ø6.0mm) 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.

Device Description & Technological Characteristics

The Xpeed® AnyRidge® Internal Implant System is especially designed for use in dental implant surgery. It consists of machined titanium, screw-form, root-form endosseous dental implant. The Xpeed® AnyRidge® Internal Implant System contains two types of fixtures, Normal ridge type and low ridge type. This system is made from CP Titanium, Gr.4 and Ti-6Al-4V, ELI and the surface treatment is done with S.L.A (Sand-blasted, Large grit, Acid-etched). The implants 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. 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 6.2, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm lengths for normal ridge and 6.4, 7.9, 9.4, 10.9, 12.4, 14.4mm lengths for low ridge fixtures. Fixtures are produced and packaged separately. All included devices in the system are covered by this submission.

The purpose of this submission is

- the addition of 6.2mm and 6.4mm length implant fixtures, Normal Ridge Type, FANIHX4507, 5007, and 5507, and Low Ridge Type, FALHX 6007, 6507, 7007, 7507, and 8007
- the addition of two surgical instrument kits, KARIN 3000 and 30001 and All-in-one case

Predicate devices

- EZ PLUS Internal Implant System (K070562)
- XpeedAnyRidge Internal Implant System (K122231)

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 similar in size and materials.

There is no difference between the subject and predicate with respect to the indications or technology.

	Subject Device	Predicate Device	Predicate Device
510(k) Number	Not available yet	K122231	K070562
Device Name	XpeedAnyRidge Internal Implant System	XpeedAnyRidge Internal Implant System	EZ PLUS Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
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	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	EZ PLUS 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
Material	CP Titanium, Gr.4 and Ti-6Al-4V, ELI	CP Titanium, Gr.4 and Ti-6Al-4V, ELI	CP Titanium, Gr.4 and Ti-6Al-4V, ELI
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)	Internal type: 3.3, 4.0, 5.0mm External type: 3.3, 4.0, 5.0mm
Fixture Height	Internal type 6.2, 7.7, 9.2, 10.7, 12.2,	Internal type 6.2, 7.7, 9.2, 10.7, 12.2,	Internal type: 8.0, 10.0, 11.0, 13.0,15.0,

		14.20, 17.2mm (For normal ridge) 6.4, 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)	14.20, 17.2mm (For normal ridge) 6.4, 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)	18.0mm External type: 8.0, 10.0, 11.0, 13.0, 15.0, 18.0mm
Abutment	Diameters	Ø 4.0 – 10.0mm	Ø 4.0 – 10.0mm	Ø 4.0 – 6.0mm
	Lengths	8.4 – 16.4mm	8.4 – 16.4mm	9.0 – 17.2mm
Angulations of Angled abutments		15, 25°	15, 25°	15, 25°
Product Code		DZE, NHA	DZE, NHA	DZE, NHA
Surface treatment		SLA	SLA	RBM

Non-Clinical Test Data

No additional testing was added for this submission.

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 safe and effective and substantially equivalent to predicate devices as described herein.



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

March 27, 2013

MegaGenImplant Company, Limited
C/O Ms. April Lee
KoDent, Incorporated
325 North Puente Street, Unit B
BREA CA 92821

Re: K123870

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: February 14, 2013
Received: February 25, 2013

Dear Ms. 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. 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kwame O. Ulmer
-S  for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K123870

Device Name: Xpeed® AnyRidge® Internal Implant System

Indications for Use:

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Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runney, DDS, PA 2013.03.22
09:20:02-04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123870