510(K) Summary

MAR 2 2 2011

Submitter:

Cho Sung Am
CSM Implant Co., Ltd.
702-020, B205 Techno B/D,
Kyung-Buk National University
573-13, Bokhyun-dong,
Buk-gu, Daegu, South Korea
Phone: +82-53-952-8261
Fax: +82-53-954-8261

US Agent / Official Contact:

Joyce Bang
Kodent Inc.
325 N Puente st. Unit B
Brea, CA 92821
Phone: 714-525-0114
Fax: 714-525-0116
Email: kodentinc@gmail.com

Device Information

Trade Name: CSM submerged-L Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: Aug, 2010

General Description

The CSM submerged-L Implant System includes various one-stage Fixtures and two-stage Fixtures made of titanium. These implants are surgically inserted into the upper and/or lower jawbone and serve as a tooth root replacement providing a stable foundation for restorations.

This product is a fixture and an abutment prosthetic dentistry material which are dental implant infrastructures. The connection with the abutment is inserted in bones as internal connection (the morse taper 11° and Hexagon type) method. A connection will restore mastication function of the patient who has difficulties due to damage of the natural tooth and function as a supporting the prosthetic dentistry material such as artificial tooth.

Indication for Use

CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.

Predicate Devices & Comparison
The subject device is substantially equivalent to the following predicate device:

- Biohorizos Internal Implant system(K073268)

Testing and other comparisons have established that the subject of CSM submerged-L Implant System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to the predicate device currently marketed in the U.S.

6.2 Substantial equivalence chart

		Subject Device	Predicate Device
510(K) Number		N / A	K073268
Device Name		CSM submerged-L Implant System	BioHorizons Internal Implant System
Manufacturer		CSM Implant	BioHorizons Implant Systems, Inc.
Indications for Use		Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design		Similar to internal Implant Design with a narrower shape towards the bottom	Similar to internal implant design with a narrower shape towards the bottom
Endosseous Implant Material		Ti-6Al-4V ELI ASTM-F136	Ti-6Al-4V ELI ASTM-F136
Implant Sterile		Yes	Yes
Implant Sterilization Method		Gamma	Gamma
Surface Treatment		RBM (Resorbable Blasting Media) + Laser	RBT (Resorbable Blast Texture)/HA (Hydroxylapatite) + Laser-Lok
Implant	Diameters	3.5 – 6.0 mm	3.5 – 6.0 mm
	Lengths	7 – 14 mm	9 – 15 mm
Attachments		Various abutments and components	Various abutment and component
Abutment Material		Ti-6Al-4V ELI ASTM-F136	Ti-6Al-4V ELI ASTM-F136
Product Code		DZE	DZE

Performance Data

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, mechanical testing of the implants demonstrated that the CSM submerged-L Implant System possess mechanical strength at least equivalent to the predicate devices.

Among the information and data presented in this 510(k) submission to support the substantial equivalence of the CSM submerged-L Implant System to the specified predicate devices, fatigue testing demonstrated that there is substantial equivalence in the performance between the CSM submerged-L Implant System and the referenced predicate devices. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use.

Safety and Effectiveness

CSM submerged-L Implant System is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. The CSM submerged-L Implant System, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

Conclusion

The CSM submerged-L Implant System, subject of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. The risks of using the device as recommended pose no greater risks than other implant systems. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, CSM submerged-L Implant System and its predicate devices are believed to be substantially equivalent.

Indication for Use

510(K) Number (if known): K102635

Device Name: CSM submerged-L Implant System

CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CSM Implant Company, Limited
C/O Ms. Joyce Bang
Kodent, Incorporated
325 North Puente Street, Unit B
Brea, California 92821

MAR 2 2 2011

Re: K102635
Trade/Device Name: CSM Submerged-L Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 9, 2011
Received: March 16, 2011

Dear Ms. Bang:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K102635

Device Name: CSM submerged-L Implant System

CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

510(k) Number: K102635