K070569

510(K) SUMMARY

SM® Internal/External Implant Systems

14-1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, South Korea Phone: 82-55-363-3401 Fax : 82-55-363-3404
14-2. US Agent / Contact Person	Kenny Lim 13340 E. Firestone Blvd. Suite J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
14-3. Date Prepared	February 09, 2007
14-4. Device Name	SM® INTERNAL/EXTERNAL IMPLANT SYSTEMS
14-5. Classification Name	Endosseous Dental Implant System
14-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number:
14-7. Predicate Devices	SM® IMPLANT SYSTEMS
14-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

NOV 0 8 2007

14-9. Device Description

SM® Implant System is a root-form threaded dental implant made of Grade 3 and Grade 4 titanium. The implant is produced by machining process, followed by grit blasting and cleaning. It is available in diameters 3.8, 4.5 and 5.3mm, and lengths from 8mm to 14mm. It is placed via one or two stage surgery and the functional loading can be from immediate to delay.

14-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. SM ™ Implant Systems (SM ™ Implant Fixtures, SM Protective Cap, and SM Implant System Surgery Tray) will be packaged.

14-11. Intended Use

The SM Dental implant system is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. The SM Dental implant system is intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients 4 or more implants must be used.

14-12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Device Name	DIO DENTAL IMPLANT CO. LTD (SM® Internal/External Implant System)	DIO DENTAL IMPLANT CO. LTD **(K061797)** (SM® Implant System)
Intended Use	Identical to predicate devices	DIO Dental implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, terminal or intermediate abutment for fixed bridgework, partial dentures, or single tooth replacements.
Material	Commercially pure titanium GR. 3 and GR.4 (ASTM-F-67)	Commercially pure titanium GR. 3 and GR.4 (ASTM-F-67)

Design	Morse Taper with Thread	Morse Taper with Thread
Screw Threads	YES	YES
Implant Thread Diameter (mm)	3.8, 4.5, and 5.3 mm	3.8, 4.5, and 5.3 mm
Collar Height (mm)	1.8	1.8
Lengths(External)	8-14 mm	8-14 mm
Surface Treatment	Machined	Machined
Gamma sterilized	YES	YES

Attachments

Screw-retained restoration system	YES	YES
Cemented restoration system	YES	YES
Overdenture restoration	YES	YES
Instruments (surgical and restorative)	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

DIO Department DSI, Incorporated
C/O Mr. Hosup Shim
KoDent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K070569
Trade/Device Name: SM Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 29, 2007
Received: October 29, 2007

Dear Mr. Shim:

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.

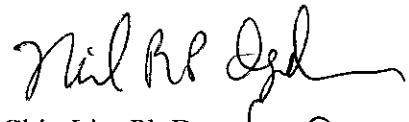
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K070569

Device Name: SM Dental Implant System

Indications For Use:

The SM Dental implant system is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. The SM Dental implant system is intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients 4 or more implants must be used.

Prescription Use ___X___ AND/OR ___ Over – The-Counter Use

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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