OCT 09 2008

Attachment 4.

K080559

510(k) Summary

DIO SM Implant System

1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, Korea Phone: 82-55-383-7900 Fax : 82-55-363-3404
2. US Agent / Contact Person	Hyungick Kim 3540 Wilshire Blvd. #1104 Los Angeles, CA 90010, USA Phone : 213-365-2875, Fax : 213-365-1595
3. Date Prepared	January 08, 2008
4. Device Name	DIO SM IMPLANT SYSTEM
5. Classification Name	Endosseous Dental Implant System
6. Device Classification	Class II Dental Devices panel Regulation Number: 21 CFR 872.3640
7. Predicate Devices	SM Implant System(510(k) No: K061797)
8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.
9. Purpose	The purpose of this 510(k) is to modify the prior 510(k) submission for the SM Implant System

10. Device Description

The DIO SM Implant System is comprised of dental implants, Superstructures, Instruments for prosthetics and Surgical Instruments.

The DIO SM Implant System is specially designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm implant when surgically implanted under controlled conditions, per well known clinical studies. There are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations.

11. Packing / Labeling / Product Information

DIO SM Implant System follows the guidance of the 21 CFR 872.3640..

12. Intended Use

The DIO SM Implant System is an endosseous dental implant is indicated 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. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four interforminal placed implants, and not indicated for single unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

13. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	**Predicate Device**
Manufacturer Name	DIO Department, DSI, Inc.	DIO Department, DSI, Inc.
Device Name	DIO SM Implant System	SM Implant System
510(k) Number	Not available yet	K061797

	Subject Device	Predicate Device
Intended Use	Same with predicate device	The DIO SM Implant System is an endosseous dental implant is indicated 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. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four interforminal placed implants, and not indicated for single unsplinted implants. Patients must be subject for dental treatment with endosseous implants.
Material	CP Ti Gr4	CP Ti Gr4
Design	Internal Type and Morse Tapered	Internal Type and Morse Tapered
Screw Threads	YES	YES
Implant Diameters(mm)	3.8/4.5/5.3	36.8/4.1/4.5/5.0/5.3
Implant Lengths(mm)	7/8.5/10	7.0-12.5
Surface Treatment	RBM (Resorbable Blast Media)	RBM (Resorbable Blast Media)
Sterilization Method	GAMMA	GAMMA
Attachments	Various abutments and components	Various abutments and components
Product Code	DZE	DZE

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

DIO Department, DSI, Incorporated
C/O Mr. Hyungick Kim
Manager
DIO, USA
3540 Wilshire Boulevard, Suite 1104
Los Angeles, California 90010

Re: K080559
Trade/Device Name: DIO SM Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 19, 2008
Received: September 30, 2008

Dear Mr. Kim:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2.

Indication for Use

510(K) Number (if known): K080559

Device Name: DIO SM Implant System

Indications For Use:

The DIO SM Implant System is an endosseous dental implant is indicated 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. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four interforminal placed implants, and not indicated for single unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

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

510(k) Number: K080559

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)

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