Attachment 4

510(k) Summary

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

1. Submitter	DIO Corporation 1464 U-dong, Haeundae-gu, Busan, 612-020, Korea Tel. : 82-51-745-7777 Fax. : 82-51-745-7779
2. US Agent / Contact Person	DIO, USA Tim C.J. Lee 3540 Wilshire Blvd. #1104 Los Angeles, CA 90010, USA Tel. : 213-365-2875 Fax. : 213-365-1595
3. Trade Name	DioSlimon Implant System
4. Common Name	Dental Implant
5. Classification Name	Endosseous Dental Implant 21 CFR 872.3640 Class II DZE
6. Predicate Devices	DIO Protem Implant System(2.0/2.5mm) (K080126)

7. Device Description

DioSlimon Implant System consists of Dental Implants, Superstructure, Instruments of Prosthetic and Surgical Instruments.

The Dental Implant of the DioSlimon Implant System is an integrated system of endosseous dental implant which designed to protect main implant from immediate loading during osteointegration period, to increase indurance of temporary tooth and to

conduct the immediate functions and immediate recovery of aesthetics of osteoimplanted area. These are made of Titanium Alloy(Ti-6Al-4V ELI / ASTM F136) which have a sand-blasted, RBM(Resorbable Blast Media) treated surface. These implants are consist of one-stage, root-form dental implant which provide the clinician to maintain the patients' gingival contour. The Implants have the diameter(2.0/2.5mm) and length(8/10/12/14mm).

The superstructure consists of Ball Cap. Ball Cap intended to retain the O-ring inside of the denture.

The Instruments of Prosthetic and Surgical Instruments provide the clinician to choose only those components required for each clinical situation.

The Dental Implant is gamma sterilized and intended to single use. And the others are non-gamma sterilized. It have to be sterilized by user before using.

8. Intended Use

The DioSlimon Implant System is intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

9. Performance

Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

10. Packing / Labeling / Product Information

DioSlimon Implant System follows the guidance of the 21 CFR872.3640.

11. Substantial Equivalence Comparison

	Subject Device	Predicate Device

Manufacturer Name	DIO Corporation	DIO Department, DSI, Inc.
Device Name	DioSlimon Implant System	DIO Protem Implant System(2.0/2.5mm) (K080126)
Intended Use	Same with predicate device	The DIO Protem Implant System (2.0/2.5mm) is intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Screw Threads	YES	YES
Implant Diameters(mm)	2.0/2.5	2.0/2.5
Implant Lengths(mm)	8/10/12/14	8/10/12/14
Surface Treatment	RBM (Resorbable Blast Media)	RBM (Resorbable Blast Media)
Sterilization Method	Gamma	Gamma
Attachments	Various abutments and components	Various abutments and components

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

12. Conclusion

The evaluation of the DioSlimon Implant System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

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

OCT 21 2011

DIO Corporation
C/O Mr. Timothy Lee
Manager
DIO USA
3540 Wilshire Road, Suite 1104
Los Angeles, California 90010

Re: K112746
Trade/Device Name: DioSlimon Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 1, 2011
Received: September 21, 2011

Dear Mr. 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,

Anthony D. Watson

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

K112946

Attachment 2

Indications for Use Statement

510(K) Number (if known) : _____

Device Name : DioSlimon Implant System

Indications For Use :

The DioSlimon Implant System is intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase fo permanent endosseous dental implants.

Prescription Use ___✓___ AND/OR _____ Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)

Susan Runner

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

510(k) Number: K112946