K100100

NOV 10 2010

Attachment 4

510(k) Summary

DIO STEADY External Implant System

1. Submitter	DIO Corporation 1464 U-dong, Haeundae-gu, Busan, 612-020, Korea Tel. : 82-51-745-7777 Fax. : 82-51-745-7778
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. Device Name	DIO STEADY External Implant System
4. Classification Name	Endosseous Dental Implant System
5. Device Classification	Class II Dental Devices panel Regulation Number: 21 CFR 872.3640
6. Predicate Devices	SM Internal/External Implant System(510(k) No: K070569)
7. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.
8. Purpose	The purpose of this 510(k) is to modify the prior 510(k) submission for the DIO STEADY External Implant System.

K100100

9. Device Description

The DIO STEADY External Implant System is comprised of dental implants, and superstructures.

The DIO STEADY External 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.

10. Packing / Labeling / Product Information

DIO STEADY External Implant System follows the guidance of the 21 CFR872.3640.

11. Intended Use

The DIO STEADY External 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 interforaminal placed implants, and not indicated for single unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

K100100

12. Substantial Equivalence Comparison

Technological Characteristic Comparison

	Subject Device	Predicate Device
Manufacturer Name	DIO Corporation	DIO DENTAL IMPLANT CO., LTD
Device Name	DIO STEADY External Implant System	SM Internal/External Implant System
510(k) Number	Not available yet	K070569
Intended Use	Same with predicate device	The DIO Dental Implant is an 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	CP Ti Gr4 (ASTM F67)	CP Ti Gr4 (ASTM F67)
Design	External Hex Type	Internal Type, Morse Tapered and External Hex Type
Screw Threads	YES	YES
Implant Diameters(mm)	3.3/3.75/4.0/4.5/5.0/6.0	3.8/4.5/5.3
Implant Lengths(mm)	8.5/10/11.5/13/15/16	8/10/12/14
Surface Treatment	RBM (Resorbable Blast Media : TiO_2 100%)	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

K100100

13. Review

The DIO STEADY External Implant System has same material and indication for use and similar design and technological characteristics as the predicate device.

The DIO STEADY External Implant System has been subjected to safety, performance and product validation prior to release. Safety tests including biocompatibility has been performed to ensure the devices comply with the applicable International and US regulations.

14. Summary of nonclinical testing

Fatigue testing was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the DIO STEADY External Fixture and an angled abutment.

The fatigue test results were similar to previously cleared predicate devices.

15. Conclusion

The evaluation of the DIO STEADY External Implant System demonstrates that it may be considered substantially equivalent to its predicate device.

Date: October/ 30/ 2009

Gabmoon,Jeong/ DIO Corporation RA Staff

Date: October/ 30/ 2009

Tim C.J. Lee/ DIO, USA Manager

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

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

NOV 10 2010

Re: K100100
Trade/Device Name: DIO STEADY External Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 7, 2010
Received: October 19, 2010

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,

for Susan Runner

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

Attachment 2

Indications for Use Statement

NOV 1 0 2010

510(K) Number (if known): K100100

Device Name: DIO STEADY External Implant System

Indications For Use:

The DIO STEADY External 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 interforaminal placed implants, and not indicated for single unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

Prescription Use ✔ 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)

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

510(k) Number: K100100