JUL 12 2005

K043428

A 510(k) Summary Pertaining to the Safety and Effectiveness of the Reliadent Dental Implant System

Submitter Information:
Chan Q. Wang
President
Bioinfera, Inc.
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Date Summary Prepared: December 7, 2004

Device Name:
Proprietary name – Reliadent Dental Implant System
Common/Usual name – Implant, Endosseous, Root Form
Trade name – Reliadent Dental Implant System

This device has been classified Class II Special Controls.
Classification number: DZE.
Regulation Number: 21 CFR 872.3640.
Classification Advisory Committee: Dental

Predicate Device:
MIS Dental Implant System
510(k) – K040807
Cleared – June 6, 2004

Description of the Device:

The Reliadent Dental Implant System includes surgical implants, healing cap, restoration abutments, and surgical instruments.

Implants:

Includes one or two step dental implant devices which are designed as conical and cylindrical shapes. They consist of various diameters with a range of 3.6mm-6.0mm and lengths with a range of 8mm-17mm. The internal and external hexagonal shapes are important to maintain the implant stability. One group of the products is HA coated. This surface has been modified to enhance the osseointegration. The dental implants are composed of medical grade 4 pure titanium.

Cover screw and healing cap:

The cover screw and healing caps are supplied together with the implants. They cover the internal body of implant to allow gum free space for connection between the implants and restoration abutments.

Abutment:

Abutments and accessories are the support part to prosthetic restoration. Screw retained abutments are included in the Reliadent Dental Implant System. The abutments are composed of medical grade 2 titanium.

Surgical Instrument Kit:

The surgical instruments include the implants installation set, abutment connections, and drill set. There are hand tools, drill bits of different sizes, and handles in these sets. The instrument kit is designed to be used with a wide range of commercially available implant devices.

Indications for Use:

Indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Substantial Equivalence:

The Reliadent Dental Implant System has the same intended use as the MIS Dental Implant System from MIS Technologies, Inc. Elmwood Park, NJ 07407, cleared under 510(k) Number: K040807. The MIS Dental Implant System has equivalent performance characteristics in its intended use, material and design. The MIS Dental Implant System contain implants, cover screw and healing caps, abutments and the applicable surgical instruments. The Reliadent Dental Implant System is substantially the same as the currently marketed MIS dental implant with a modified surface. This surface promotes osseointegration. All other technological characteristics are similar and both devices show equivalent performance capabilities.

Conclusion:

The evaluation of the Reliadent Dental Implant System does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Mr. Chan Q. Wang
President
Bioinfera, Incorporated
21205 Halworth, Road
Beachwood, Ohio 44122

Re: K043428
Trade/Device Name: Reliadent Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: NHA
Dated: July 1, 2005
Received: July 5, 2005

Dear Mr. Wang:

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.

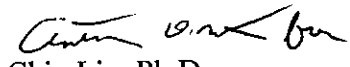
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K043428

Device Name: Reliadent Dental Implant System

Indications for Use: Indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mealy for ASR

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

510(k) Number K043428