1 of 1

K080713

Implant Direct LLC
www.implantdirect.com

ReActive Dental Implant System
Traditional 510(K) Submission

510(K) Summary (21CFR 807.92(a))

MAY 16 2008

1. **Submitter's Information**
Company Name: Implant Direct LLC
Address: 27030 Malibu Hills Rd., Calabasas Hills, CA USA 91301
Telephone Number: 818-444-3300
Fax Number: 818-444-3400
Registration Number: 3001617766
Contact Person: Tom Gottenbos
Date Summary Prepared: January 14, 2008
Classification Name: Implant, Dental, Endosseous
Common/Usual Name: Endosseous Dental Implant

2. **Device Trade Name:** ReActive Dental Implant System

3. **Predicate Device(s):** Implant Direct's Spectra-System (K061319) and RePlus Implants With HA Coating (K073161)

4. **Device Description:**
The ReActive Implant system consists of tapered screw-type endosseous implants with the same standard thread configuration, the same 2mm of mini-threads near the top of each implant, are manufactured using the same medical grade titanium alloy material and are textured with the same soluble blast media (SBM)

5. **Intended Use:**
The intended use of the ReActive dental implants is identical to the intended use of the predicate implants. These implants are two-piece implants for single-stage or two-stage surgical procedures. The ReActive implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

6. **Device Comparison:**
ReActive dental implants compare favorably to similar devices found within the cited predicates. The implants within this submission are used in an identical function as the cited predicates. The implants within this submission have nearly identical technological characteristics, intended use, and materials used in manufacture as the cited predicates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas Gottenbos
Vice President of IT/Regulatory Affairs
Implant Direct LLC
27030 Malibu Hills Road
Calabasas Hills, California 91301

MAY 16 2008

Re: K080713
Trade/Device Name: ReActive Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 15, 2008
Received: March 13, 2008

Dear Mr. Gottenbos:

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.

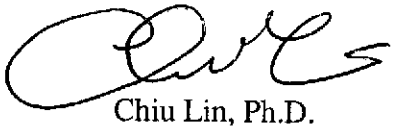
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K080713

1 of 1

Indications for Use

510(k) Number (if known): _____

Device Name: ReActive Dental Implant System

Indications for Use:

The ReActive Dental Implant System are dental implant fixtures that are a part of a two-piece implant system. The ReActive implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mealy for MSR

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

510(k) Number: K080713