K080633

Implant Direct LLC
www.implantdirect.com

JUL 15 2008

ScrewIndirect Narrow Dental Implants
Traditional 510(K) Submission

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

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: June 27, 2008
   Classification Name: Implant, Dental, Endosseous
   Common/Usual Name: Endosseous Dental Implant

2. **Device Trade Name:** ScrewIndirect Dental Implants

3. **Predicate Device(s):** Implant Direct's Spectra-System (K061319)

4. **Device Description:**
   The ScrewIndirect Narrow Dental Implants consist of tapered screw-type endosseous implants with the same standard "V" 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 coated with the same soluble blast media (SBM). The 3.0mmD implants are in addition to previously approved implants in this system, and are the sole subject of this submission.

5. **Intended Use:**
   ScrewIndirect Narrow Dental Implants are implants for single-stage surgical procedures intended for use in partially or fully edentulous mandibles and maxillae, in support of complete or partial denture prostheses or as a terminal or intermediary attachment for fixed or removable bridgework via interface with copings. These implants are intended for immediate loading for support of splinted multiple tooth restorations, provided initial implant stability and appropriate occlusal load requirements are met.

6. **Device Comparison:**
   This submission comprised of implants whose physical dimensions, material composition, and manufacture were approved in a previous 510K (K061319) but are now being offered an additional diameter. The ScrewIndirect implants approved under K061319 were offered in the 3.7mm, 4.7mm, and 5.7mm body diameter. This submission adds a 3.0mm body diameter to this product family. The smaller diameter reduces the requirements made for the buccal-lingual bone dimension, permitting placement in areas with less bone availability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2008

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

Re: K080633
Trade/Device Name: ScrewIndirect Narrow Dental Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 27, 2008
Received: July 1, 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,

for 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): K080633

Device Name: ScrewIndirect Narrow Dental Implants

Indications for Use:

ScrewIndirect Narrow Dental Implants are implants for single-stage surgical procedures intended for use in partially or fully edentulous mandibles and maxillae, in support of complete or partial denture prostheses or as a terminal or intermediary attachment for fixed or removable bridgework via interface with copings. These implants are intended for immediate loading for support of splinted multiple tooth restorations, provided initial implant stability and appropriate occlusal load requirements are met.

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)

R S Betz DDS for Dr. Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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