



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 26 2006

Ms. Patty McMahon  
Vice President  
Implant Direct, LLC  
27030 Malibu Hills Road  
Calabasas Hills, California 91301

Re: K061319  
Trade/Device Name: Spectra Dental Implant System  
Regulation Number: 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: July 28, 2006  
Received: July 31, 2006

Dear Ms. McMahon:

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): K061319

Device Name: Spectra Dental Implant System

## Indications for Use:

The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established.

The ScrewDirect 3.0mm implant is indicated for:

1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
2. Multiple tooth replacements or denture stabilization.

The Screw Redirect implant is intended for support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of the partially edentulous maxillary jaw. It is indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw.

The Screw Indirect implant is indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw-retained fixed bridgework. It is indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw. This implant model is not indicated for use with abutments, only with a 2mm extender.

Prescription Use    
 (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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert E. Betz DDS for Dr. Susan Runner*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K061319