Implant Direct LLC
www.implantdirect.com

K081396

JAN 14 2009

Swiss Plant Dental Implant System
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: April 18, 2008
Classification Name: Implant, Dental, Endosseous
Common/Usual Name: Endosseous Dental Implant

2. **Device Trade Name**: Swiss Plant Dental Implant System

3. **Predicate Device(s):** Sulzer Dental SwissPlus Implant System (K011245),

4. **Device Description:**
The SwissPlant Dental implant system consists of implants, abutments, healing components, fixation screws and surgical armamentaria for use in one or two-stage placement and restorations.

5. **Intended Use:**

The SwissPlant Dental Implant system consists of two-piece implants for one 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 including: cement retained, screw retained or overdenture restorations and in terminal or immediate abutment support for fixed bridgework. The SwissPlant dental implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing initial implant stability and appropriate occlusal loading, to restore normal masticatory function.

6. **Device Comparison:**
This submission is comprised of devices whose physical dimensions, material composition, indications for use and methods of manufacture were previously approved and have the same principles of operation as the cited predicate devices. The differences between the components included in this submission and their predicate devise pose no new or additional issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas Gottenbos
Vice President
Implant Direct LLC
27030 Malibu Hills Road
Calabasas Hills, California 91301

JAN 14 2009

Re: K081396
Trade/Device Name: SwissPlant Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 22, 2008
Received: December 29, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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): K081396

Device Name: SwissPlant Dental Implant System

Indications for Use:

The SwissPlant Dental Implant system consists of two-piece implants for one 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 including: cement retained, screw retained or overdenture restorations and in terminal or immediate abutment support for fixed bridgework. The SwissPlant dental implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing initial implant stability and appropriate occlusal loading, to restore normal masticatory function.

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)

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

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