OCT 2 8 2004

510(k) Summary

K041271

Trade Name: **Sterngold 3.25mm ERA Dental Implant System**

Sponsor: Sterngold
23 Frank Mossberg Drive
Attleboro, MA 02703

Device Generic Name: Dental endosseous implant system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class ~~III~~ II

Product Code: DZE (21CFR872.3640)

Predicate Devices:
The Sterngold 3.25mm ERA Dental Implants are substantially equivalent to other currently marketed dental implant systems that have been cleared by FDA through the 510(k) Premarket Notification process, including the Sterngold ERA Dental Implant System and the Sterngold Narrow Platform Hex Screw Implants.

Product Description:
The Sterngold 3.25mm ERA Dental Implant System consists of a threaded, external-hex, self-tapping, root-form endosseous implant with integral female insert (abutment). The thread major diameter is 3.25 mm; available implant lengths will be 10, 13 & 15 mm. The implants will be available in straight and angle-correction (5°, 11° & 17°) versions with cuff heights ranging from 0.76 – 4mm. The implants are manufactured from pure, implant-grade titanium alloy. The external surface of the implants (excluding the neck and the implant head) is lightly acid etched to remove any surface contaminants remaining from the manufacturing operation, and to achieve a slightly roughened microsurface to aid in implant osseointegration. The female insert is titanium nitride coated.

Indications for Use:

The Sterngold 3.25mm ERA dental implants are intended for permanent as well as temporary surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function. Immediate loading of the ERA Implant should only occur when the position of the implants provides adequate bone quantity and quality to allow proper immediate mechanical stabilization of the self-tapping screw into the bone and where occlusal and lateral forces can be limited with appropriate occlusal design and a soft diet.

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Sterngold has provided information to demonstrate conformity with the following standards:

- ***Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants*** (FDA Guidance)
- ***Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants*** (FDA Guidance; December 9, 1996)

Conclusion:
Based on their indications for use, technological characteristics, and comparison to predicate devices, the Sterngold 3.25mm ERA Dental Implant System has been shown to be safe and effective for the product's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2004

Sterngold
C/O Ms. Pamela Papineau
Regulatory Affairs Consultant
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K041271
Trade/Device Name: 3.25mm ERA Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: August 20, 2004
Received: August 23, 2004

Dear Ms. Papineau:

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/dsma/dsmamain.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

510(k) Number (if known): K041271

Device Name: 3.25mm ERA Dental Implant System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

Susan Runner

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

510(k) Number: K041271