



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 7, 2015

Sterngold Dental LLC
Ms. Maria Rao
Director of Regulatory Affairs
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703

Re: K142667
Trade/Device Name: Stern AC Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 11, 2014
Received: December 12, 2014

Dear Ms. Rao:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. In the background, there is a faint, semi-transparent watermark of the FDA logo.

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K142667

Device Name: Stern AC Dental Implant System

Indications for Use:

The Stern AC Dental Implant System can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The Stern AC Dental Implant System is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The Stern AC Dental Implants are compatible with the Straumann Rn Synocta, Straumann SynOcta Meso Abutments, Straumann RC Temporary Abutments, Straumann RC Cementable abutments and Stern IC Solid Abutments.

The Stern AC Dental Implant System is only intended for use with straight abutments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the -Counter Use _____
(21 CFR 807 Subpart D)

510(k) Summary

K142667

Trade Name: Stern AC Dental Implant System

Sponsor: Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

Contact: Maria Rao, QA/RA Director
Ph: 508-226-5660 ext 1206

Date: January 5, 2015

Device Generic Name: Endosseous Dental Implant system

Classification: Endosseous Dental Implant, 872.3640, Class II

Product Code: DZE

Predicate Devices:

The Stern AC Dental Implant System is 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 Acid Etch Dental Implant System (K023580), and Stern IC Dental Implant System (K111798).

Product Description:

The proposed implant is a self-tapping, double thread screw implant, manufactured from pure grade 4 titanium. The implant is acid etched except for the neck, which is machined to a smooth finish. Stern AC Implants are manufactured with a flared neck, used for one-stage, transgingival implantation. The neck and body include an internal taper and octagon. The implants are manufactured with three body diameters, 3.3 mm, 4.0 mm, and 5.0 mm, all with the same prosthetic head.

The proposed implants are prosthetically compatible with the Straumann ITI implant system and the Stern IC Dental Implant System previously approved for market:

Straumann Rn Synocta - K073628
Straumann SynOcta Meso Abutments - K033243
Straumann RC Temporary Abutments - K093027
Straumann RC Cementable abutments - K072071
Stern IC Solid Abutments - K111798

They are packaged sterile in a double blister, which contains implant with an implant mount and mount screw secured in a titanium tube. The Mount Body is screwed into the implant hex using the mount screw, which keeps it in place. This configuration is known as "Direct Delivery", which allows the surgeon to transport the implant from the package to the prepared implant site and save chairside time. The proposed Stern AC Dental Implant will be available in a range of lengths and diameters.

Thread Major Diameter (mm)

3.3mm
4.0 mm
5.0mm

Overall Implant Length (mm)

10.0, 11.5, 13.0mm
8.5, 10.0, 11.5, 13.0, 15.0mm
8.5, 10.0mm

The Stern AC Dental Implant System is not intended for correction of implant fixtures placed at an angle. It is only intended for use with straight abutments.

Indications for Use:

The Stern AC Dental Implant System can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The Stern AC Dental Implant System is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The Stern AC Dental Implants are compatible with the Straumann Rn Synocta, Straumann SynOcta Meso Abutments, Straumann RC Temporary Abutments, Straumann RC Cementable abutments and Stern IC Solid Abutments. The Stern AC Dental Implant System is only intended for use with straight abutments.

Substantial Equivalence:

The proposed Stern AC 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. The intended use, basic design, fundamental operating principles are the same as the predicate devices.

- Stern IC Dental Implant System (K111798)
- Sterngold Acid Etch Dental Implant System (K023580)

Technological Characteristics:

The Stern AC dental Implant provides the same or similar functions as well as design and technological characteristics as the predicate devices listed. In addition the surface is identical to the cleared Sterngold Acid Etched Implant.

The materials, technology and facilities used to produce the Stern AC Dental Implants are the same as other Sterngold Dental Implants previously approved and cleared by FDA.

The proposed Stern AC dental implant has the same materials, same manufacturing process and surface treatment as previously cleared Sterngold Acid Etch dental implant and Stern IC Dental Implant. This surface is widely used in the industry primarily by the Straumann Company under the name "SLA".

Property	Stern AC Dental Implant System (Proposed Device)	Sterngold Acid Etch Dental Implant System (K023580)	Sterngold Stern IC Dental Implant System (K111798)
Implant Design	Self-tapping, threaded, Root-form implant	Self-tapping, threaded, Root-form implant	Self-tapping, threaded, Root-form implant
Implant Sizes (diameter*) x (length)	3.3x10.0mm 3.3x11.5mm 3.3x13mm 4.0x8.5mm 4.0x10.0mm 4.0x11.5mm 4.0x13.0mm 4.0x15.0mm 5.0x8.5mm 5.0x10.0mm	3.75x8.5MM 3.75X10.0MM 3.75X11.5MM 3.75X12.0MM 3.75X13.0MM 3.75X15MM 4.0X8.5MM 4.0X10.0MM 4.0X13.0MM	3.3x1.8x8.0MM 3.3x1.8x10.0MM 3.3x1.8x12.0MM 3.3x1.8x14.0MM 4.1x1.8x8.0MM 4.1x1.8x10.0MM 4.1x1.8x12.0MM 4.1x1.8x14.0MM
Abutment Compatibility	Internal Connection	External Connection	Internal Connection
Implant Stage	Stage 1 and Stage 2	Stage 1 and Stage 2	Stage 1 and Stage 2
External Screw Threads	Yes	Yes	Yes
Placement Accessories	Implant drills, twist drills, countersinks, bone taps, insertion tool	Implant drills, twist drills, countersinks, bone taps, insertion tool	Implant drills, twist drills, countersinks, bone taps, insertion tool
Supplied Sterile	Yes	Yes	Yes
Intended Use	Dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The Stern AC Dental Implant System is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading.	Implantation into any area of the partially and/or fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis. Intended for single tooth or multiple unit prosthesis.	Long term 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. Also indicated for for immediate loading with good primary stability and appropriate occlusal loading
Implant Material	CP Titanium titanium grade 4	CP Titanium titanium grade 4	CP Titanium titanium grade 4
Implant Surface	Blasted with aluminum oxide particles and acid etched	Blasted with aluminum oxide particles and acid etched	Blasted with aluminum oxide particles and acid etched

Performance Testing:

Non clinical Testing was performed following "Guidance for Industry and FDA Staff -Class 11 Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments." Performance testing demonstrated that the device performs appropriately for the proposed indications for use. SEM photographs are enclosed showing all residue of blasting material was removed from the surface.

Sterilization validation was conducted on the proposed devices.

Conclusion:

Based on our analysis, the device is substantially equivalent in intended use, material, design and performance to its predicate devices, Sterngold Acid Etch Dental Implant System (K023580) and Stern IC Dental Implant System (K111798).