



Food and Drug Administration  
10903 New Hampshire Avenue  
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July 24, 2015

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

Re: K150968  
Trade/Device Name: TRU Dental Implant System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: June 26, 2015  
Received: June 30, 2015

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 Runno DDS, MA". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark logo that appears to be the letters "FDA" in a stylized font.

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): K150968

Device Name: TRU Dental Implant System

**Indications for Use:**

The TRU 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 TRU Implant System is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The TRU Implant System is only intended for use with straight abutments. The TRU implant body is intended to be placed such no angle correction is necessary.

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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** K150968

**Trade Name:** TRU 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:** July 23, 2015

**Device Generic Name:** Endosseous Dental Implant

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

**Product Code:** DZE (21CFR 872.3640)  
NHA (21CFR 872.3630)

**Predicate Devices:**

The TRU 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, and Nobel Active Internal Connection Implant System.

**Product Description:**

The TRU is a self-tapping, double thread screw implant with a micro groove section, manufactured from pure grade 4 titanium. The implant surface is acid etched. The implants are manufactured with four body diameters 3.5 mm, 4.3 mm, 5.0 mm, and 6.0 mm. The 3.5 mm implants have a Narrow Platform (NP) prosthetic head. The 4.3 mm, 5.0 mm, and the 6.0 mm implants have a Regular Platform (RP) prosthetic head. They provide for non-rotational single and multiple tooth restorations in both the maxilla and mandible. They are packaged sterile in a double blister, which contains the implant in a titanium tube. A special driver is available for the implants which simplifies implant insertion by eliminating the need for an implant mount.

The proposed TRU Dental Implant will be available in a range of lengths and diameters.

<b>Thread Major Diameter (mm)</b>	<b>Overall Implant Length (mm)</b>
3.5mm	8mm 10mm, 12mm, 14mm
4.3mm	8mm 10mm, 12mm, 14mm
5.0mm	8mm 10mm, 12mm
6.0mm	8mm, 10mm

The prosthetic components for the TRU implant System include Healing abutments, Straight Abutments and UCLA Abutments.

Healing Abutments are intended for placement onto the implant. As the tissue heals, it conforms to the contours of the abutment. As the gingiva heals, the tissue adapts to the form of the healing abutment, creating permanent oral access to the implant and prepares the gingiva for the restorative phase.

Straight Abutments attach directly to the implant and provide the transitional link between the head of the implant and the restorative components. They are designed to be used for screw retained multi-implant prostheses. They are available in a narrow platform with 1.5mm and a 3.0mm cuff size and in a regular platform with 1.5mm and a 3.0mm cuff size.

UCLA Abutments attach directly to the implant and provide a pattern for the creation of a screw retained veneered crown. They are available with two apical (bottom) ends; one with a hex to engage the hex of the implant and one without a hex that does not engage the implant. The engaging/hexed abutment is used on restoration of a single tooth to prevent rotation of the completed crown, and the non-engaging/non-hexed is used on multiple tooth restorations.

**Indications for Use:**

The TRU 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 TRU Implant System is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading.

The TRU Implant System is only intended for use with straight abutments. The TRU implant body is intended to be placed such no angle correction is necessary.

**Substantial Equivalence:**

The proposed TRU 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 Indications for Use, basic design, fundamental operating principles are the same or similar as the predicate devices.

- Nobel Active Internal Connection Implant (K071370) – **Primary Predicate**
- Sterngold Acid Etch Dental Implant System (K023580) – **Reference Predicate**

Compatibility and substantial equivalency was determined by comparing the design features including diameters, lengths, cuff sizes, materials, implant-to-abutment connection platform, implant surface texture, abutment fixation method, and intended use of proposed device to predicate devices.

Any differences between the proposed devices and predicate devices do not render the device NSE.

**Technological Characteristics:**

The TRU dental Implant provides the same or similar functions as well as design and technological characteristics as the predicate devices. In addition the surface and surface treatment is identical to the cleared Sterngold Acid Etched Implant (K023580).

The materials, technology and processes used to produce the TRU dental implants and abutments are the same as other Sterngold Dental devices previously cleared by the FDA.

See Substantial Equivalence Comparison table below.

Property	TRU Dental Implant System (Proposed Device)	Nobel Active Internal Connection Implant (K071370)  Primary Predicate	Sterngold Acid Etch Dental Implant System (K023580)  Reference Predicate
<b>Implant Design</b>	Self-tapping, threaded, Root-form implant	Self-tapping, threaded, Root-form implant	Self-tapping, threaded, Root-form implant
<b>Implant Sizes diameter x length</b>	3.5x8mm,10mm,12mm,14mm 4.3x8mm,10mm,12mm,14mm 5.0mmx8mm,10mm,12mm 6.0mmx8mm,10mm,12mm	3.5x8.5mm,10mm,11.5mm,13mm,15mm 4.3x8.5mm,10mm,11.5mm,13mm,15mm	3.3x10mm,11.5mm,13mm 4.0x8.5mm,10mm,11.5mm,13mm,15mm 5.0x8.5mm,10mm
<b>Abutment Compatibility</b>	Internal Connection	Internal Connection	External Connection
<b>Implant Stage</b>	Stage 1 and Stage 2	Stage 1 and Stage 2	Stage 1 and Stage 2
<b>Placement Accessories</b>	Implant drills, countersinks, bone taps	Implant drills, countersinks, bone taps	Implant drills, countersinks, bone taps
<b>Supplied Sterile</b>	Yes	Yes	Yes
<b>Intended Use</b>	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.	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.	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.
<b>Implant Material</b>	Wrought Titanium 6AL-4V ELI	CP Titanium titanium grade 4	CP Titanium titanium grade 4
<b>Implant Surface</b>	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.

Fatigue testing is not required because design features and technological features are similar to predicate devices; the implant body is not intended to be placed with any angle correction, and this submission does not contain any abutments for angle correction.

Proposed devices have the same sterilization process and radiation dose, same shelf life and bio-compatibility as previous cleared Sterngold devices, therefore sterility, shelf life and bio-compatibility testing performed on previous cleared Sterngold devices is applicable to the proposed new devices. As a result, the TRU Dental Implant System including abutments is substantial equivalent to the predicates.

**Conclusion:**

Based on the above analysis, technological characteristics and performance testing, the subject device is substantially equivalent in intended use, material, design and performance to its predicates.