



Food and Drug Administration
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February 5, 2016

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

Re: K153173
Trade/Device Name: MOR Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 30, 2015
Received: November 3, 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,

 Tina Kiang -
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for 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): K153173

Device Name: MOR Implant System

Indications for Use:

MOR Implants are self-tapping titanium threaded screws intended for long-term applications in the bone of the patient's upper or lower arch. The MOR implants may also be used for inter-radicular transitional applications.

These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulous cases, and employing minimally invasive surgical intervention.

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

(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

Trade Name: MOR 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: February 3, 2016

Device Generic Name: Endosseous Dental Implant System

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

Classification Name: Endosseous Dental Implant

Product Code: DZE (21CFR 872.3640)
NHA

Predicate Devices:

The MOR 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.

- **Primary Predicate**
IMTEC Sendax - MDI and MDI Plus (K031106)
- **Reference Predicates**
Sterngold - ERA Implant (K021045)
Intra-Lock International – Mini Drive-Lock Dental Implant System (K070601)
- Sterngold Acid Etch Dental Implant System (K023580)

Product Description:

The MOR is a self-tapping, small diameter, screw implant, manufactured from titanium alloy (6% Al, 4% V – ASTM F136). The portion of the implant that is submerged in the bone is grit blasted and acid etched. The implants are manufactured with two body diameters, 2.1 mm and 2.4 mm. They are packaged sterile in a double blister, which contains: the implant in a titanium tube. The MOR implant body is designed with an O-ball denture connection and a separate straight titanium alloy (6% Al, 4% V – ASTM F136) abutment which may be cemented over the O-ball for crown or bridge fixation.

The MOR Implant System is not intended for correction of implants placed at an angle. It is only intended for use with straight abutments. The MOR implant body is intended to be placed such that no angle correction is necessary.

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

Thread Major Diameter (mm)	Overall Implant Length (mm)
2.1mm	10mm, 13mm, 15mm
2.4mm	10mm, 13mm, 15mm

Dimensional requirements for the finished abutment:

Angulation of final abutment: No angles

Minimum and Maximum Gingival Height: 1.0 – 3.0mm

Minimum abutment post height may be fabricated to: 4.0mm

Indications for Use:

MOR Implants are self-tapping titanium threaded screws intended for long-term applications in the bone of the patient's upper or lower arch. The MOR implants may also be used for inter-radicular transitional applications.

These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulous cases, and employing minimally invasive surgical intervention.

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

Substantial Equivalence:

The MOR 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.

Indications for use are similar to predicates devices. Changes do not affect the intended use of the product. Overall operating principles and mechanism are the same.

Technological Characteristics:

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

The abutment is the same or similar to the predicate devices - intended use, design and function.

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

Any differences between the proposed devices and its predicates do not make the device not substantially equivalent. See chart below for list of similarities and differences.

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.

Proposed devices have the same sterilization process and radiation dose, same shelf life and biocompatibility as previous cleared Sterngold devices, therefore sterility, shelf life and biocompatibility testing performed on previous cleared Sterngold devices is applicable to the proposed new devices. As a result, the MOR Implant System is substantial equivalent to its predicates.

Conclusion:

Based on our analysis, technological characteristics and performance testing, the MOR Implant System is substantially equivalent in intended use, material, design and performance to its predicates.

Property	MOR Dental Implant System Sterngold Dental Proposed Device	MDI and MDI Plus Implants (K031106) IMTEC Sendax Primary Predicate	ERA Implant (K021045) Sterngold Dental Reference Predicate	Mini-Drive Lock Dental Implant (K070601) Intra-Lock Int. Reference Predicate	Implant System (K023580) Sterngold Dental Reference Predicate
Intended Use	See Indications for Use Statement above	Indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full partial edentulism, and employing minimally invasive surgical intervention.	Intended for surgical placement in edentulous anterior regions of maxillary and/or mandibular arch to provide temporary support and permit immediate stability and ongoing fixation of new or existing crown and bridge applications for full or partial dentures with minimal invasive surgical intervention	Intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications. Mini Drive-Lock TM Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.	Intended for implantation into any area of the partially or fully edentulous maxilla and mandible for the support of removable or fixed dental prosthesis. For single tooth or multiple units
Implant Design	Threaded, Root-form implant	Threaded, Root-form implant	Threaded, Root-form implant	Threaded, Root-form implant	Threaded, Root-form implant
Implant Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder
Implant Body Diameter	2.1mm, 2.4mm	2.1mm, 2.4mm, 2.9mm	2.2mm	2.0mm, 2.5mm	3.3mm, 4.0mm, 5.0mm
Implant Length	10mm, 13mm, 15mm	10mm, 13mm, 15mm, 18mm	10mm, 13mm, 15mm	10mm, 11.5mm, 13mm, 15mm and 18mm	8.5mm, 10mm, 11.5mm, 13mm, 15mm
Surface	Blasted with aluminum oxide particles and acid etched	Roughened - HA blasted	Blasted with aluminum oxide particles and acid etched	Roughened - HA blasted	Blasted with aluminum oxide particles and acid etched
Abutment Connection Style	External Connection	N/A	Internal Connection	N/A	External Connection
Prosthetic Platform	Square	Denture O-Ball	Hex	Denture O-Ball	Hex
Implant Material	Wrought Titanium 6AL-4V ELI	Wrought Titanium 6AL-4V ELI	Wrought Titanium 6AL-4V ELI	CP Titanium grade 4	Wrought Titanium 6AL-4V ELI
Manufacturing Process	Machining	Machining	Machining	Machining	Machining
Implant Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Abutment Material	Wrought Titanium 6AL-4V ELI	N/A	Wrought Titanium 6AL-4V ELI	N/A	CP Titanium grade 4
Manufacturing Process	Machining	Machining	Machining	Machining	Machining
Abutment Sterilization	Moist Heat (Steam)	N/A	Moist Heat (Steam)	N/A	Moist Heat (Steam)
Abutment Angulation	No Angles	No Angles	No Angles	No Angles	No Angles