DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 28, 2017

Re: K171728
Trade/Device Name: MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 25, 2017
Received: August 29, 2017

Dear Maria 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 (DICE) 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 (DICE) 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,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171728

Device Name
MOR 3.0mm and PUR NP 3.2mm Implant Systems
MOR 2.1x18mm and 2.4x18mm

Indications for Use *(Describe)*
The MOR™ implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
The MOR™ implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.

The PUR Implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
The PUR implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary

## 1. Submitter's Information:


Name: Sterngold Dental, LLC
Address: 23 Frank Mossberg Drive
Attleboro, MA 02703
Phone: 508-226-5660 ext 1206

Contact: Maria Rao, QA/RA Director


Date Prepared: September 28, 2017

## 2. Device Name:

Trade Name: MOR 3.0mm and PUR 3.2mm Implant Systems
MOR 2.1x18mm and 2.4x18mm

Regulation Number: 21 CFR 872.3640

Product Code: DZE, NHA

Classification Name: Endosseous dental implant

Classification: Class II

## 3. Predicate Devices:

**Primary Predicates**
Prismatik Inclusive Tapered implant - K153099
IMTEC MDI MII One-Piece Implant 2.9mm - K081653

**Reference Predicates**
Sterngold PUR Implant System - K151928
Implant Direct Spectra System Dental Implants 2008 - K090234
Sterngold MOR 2.1mm and 2.4mm - K153173

## 4. Product Description:

**PUR 3.2mm Implant System**

The PUR 3.2mm Implant System consists of 3.2mm threaded endosseous dental implants, as well as prosthetic components

The prosthetic components include a Straight Narrow Platform Slim Abutment with a 1.5mm and 3.0mm cuffs and a 0.050" Hex Prosthetic Screw. The purpose of the Slim Abutments is to provide surgical and prosthetic options for smaller spaces. They attach directly to the implant with the aid of the prosthetic screw and provide the transitional link between the head of the implant and the restorative components. These abutments are straight and not intended for angulation.

The PUR Straight Slim Abutments are similar to FDA cleared PUR Straight Abutments Narrow and Regular Platforms 1.5mm and 3.0mm cuffs (K151928). The difference is the body of the proposed Straight Narrow Platform Slim Abutment is more tapered. The abutments and prosthetic screw are made of Titanium 6AL-4V ELI. The ancillary component is a 3.2mm cover screw, which is flush with the top surface of the implant to prevent tissue and bone from growing inside

the implant. It is screwed onto the implant hex immediately after implant placement. It is made of Titanium 6AL-4V ELI.
The PUR 3.2mm implant is an endosseous dental implant made of Titanium 6AL-4V ELI with a treated roughened surface (blasted and etched). The implant body is tapered with double-lead threads and10 start micro threads at the collar. The implant lengths are 8mm, 10mm, 12mm and 14 mm. This implant The PUR 3.2mm implant features the same prosthetic platform as the 3.5mm and 4.3mm implants already cleared by FDA (K151928). The purpose of the 3.2mm PUR implant is to provide surgical and prosthetic options for smaller spaces. The PUR 3.2mm Implants will be provided "Sterile" using Gamma sterilization.

**MOR 3.0mm Implant System**
The MOR 3.0mm Implant System consists of 3.0mm endosseous dental implants.
The MOR 3.0mm implant is a one-piece endosseous dental implant, manufactured of Titanium 6AL-4V ELI. The portion of the implant that is submerged in the bone is a treated roughened surface (blasted and etched) to facilitate osseointegration. The MOR 3.0mm implant is similar in design to the MOR 2.4mm implant previously cleared by FDA. The implant lengths are10mm, 13mm, 15mm, and 18mm. The implant has two prosthetic head design options - 0-ball identical to Sterngold MOR 2.4mm Implant (K153173), and a Tapered Abutment similar to the IMTEC MDI MII One Piece Implant 2.9mm (K081653). This implant has the same design threads as the MOR 2.4mm Implant. The MOR Implants will be provided "Sterile" using Gamma sterilization.

**5. Indications for Use:**
The MOR™ implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
The MOR™ implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.

The PUR Implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.
The PUR implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.

**6. Substantial Equivalence:**
The device comparison outlined on Table 1 and Table 2 provides the similarities and substantial equivalency of the proposed devices to its predicates. The comparative data demonstrates that the MOR 3.0mm, PUR 3.2mm Dental Implant Systems, and 2.1x18mm and 2.4 x18mm Implants are substantially equivalent to the predicate devices. They have the same or similar indications for use, design and technological characteristics.
The PUR 3.2mm Dental Implants with lengths of 8, 10, 12 and 14mm are substantially equivalent to predicate devices previously cleared under K090234. The 3.2 x 8mm is similar to the 3.2 x 8mm implant approved under K090234 with same or similar indications for use. Any differences between the proposed devices and the predicate devices do not introduce new concerns in safety and efficacy and does not render the device NSE. Technological characteristics demonstrate the device is as safe and as effective as the predicate devices.

## Device Comparison – MOR 3.0mm Implant System

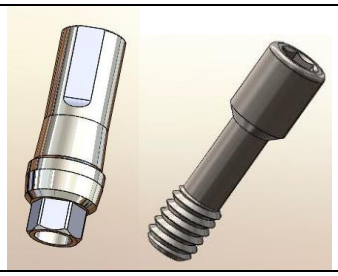
| Attributes | Proposed Devices Ø3.0mm MOR Implant | Predicate Device IMTEC MDI Ø2.9mm Implant (K081653) | Reference Predicate Sterngold MOR Dental Implant System (K153173) |
|---|---|---|---|
| **Picture of Implant** |  |  |  |
| **Implant Design** | Threaded, Root-form implant | Threaded, Root-form implant | Threaded, Root-form implant |
| **Implant Connection** | Internal Hex | Internal Hex | Internal Hex |
| **Implant Body Geometry** | Screw Type | Screw Type | Screw Type |
| **Intended Use** | The MOR™ implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The MOR™ implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary | Intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The PUR implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary | 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. |
| **Implant Material** | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI |
| **Implant Surface** | Roughened - blasted and acid etched | Roughened - blasted and acid etched | Roughened - blasted and acid etched |
| **Ø Diameters (mm)** | 3.0mm 2.1mm and 2.4mm | 2.9mm | 2.1mm, 2.4mm |
| **Lengths (mm)** | 10mm, 13mm, 15mm, 18mm | 10mm, 13mm, 15mm, 18mm | 10mm, 13mm, 15mm |
| **Sterilization** | Gamma irradiation | Gamma irradiation | Gamma irradiation |

## Device Comparison - PUR 3.2mm Implant System

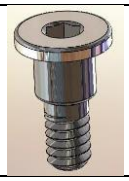
| Attributes | Proposed Device Ø3.2mm PUR Implant | Predicate Device (K153099) Prismatik Inclusive Tapered Implant | Reference Predicate Implant Direct Spectra System Dental Implants 2008 (K090234) | Reference Predicate Sterngold PUR Dental Implant System (K151928) |
|---|---|---|---|---|
| **Picture of Implant** |  |  |  |  |
| **Implant Design** | Threaded, Root-form implant | Threaded, Root-form implant | Threaded, Root-form implant | Threaded, Root-form implant |
| **Implant Connection** | Internal Hex | Internal Hex | Internal Hex | Internal Hex |
| **Implant Body Geometry** | Screw Type | Screw Type | Screw Type | Screw Type |
| **Intended Use** | The PUR Implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The PUR implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary. | Indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading. | The Spectra-System Dental Implant 2008 system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The Dental Implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occusal load requirements. | It 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 PUR Implant is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading. |
| **Implant Material** | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI |
| **Implant Surface** | Roughened - blasted and acid etched | Roughened - blasted and acid etched | Roughened - blasted and acid etched | Roughened - blasted and acid etched |
| **Ø Diameters (mm)** | 3.2mm | 3.2mm | 3.2, 3.7, 4.2, 4.7,5.2, 5.7, 7.0mm | 3.5mm, 4.3mm, 5.0mm, 6.0mm |
| **Lengths (mm)** | 8mm, 10mm,12mm, 14mm | 11.5mm, 13mm, 16mm | 8.0mm | 8.0mm, 10mm, 12mm, 14mm |

| | | | | |
|---|---|---|---|---|
| **Sterilization** | Gamma irradiation | Gamma irradiation | Gamma irradiation | Gamma irradiation |
| **Abutment Angulation** | No Angulation | 0° - 15° | No Angulation | No Angulation |
| **Abutment Material** | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI |
| **Construction** | Machined | Machined | Machined | Machined |
| **Abutment Sterilization** | Moist Heat | Moist Heat | Moist Heat | Moist Heat |

## PUR NP Slim Abutments and Prosthetic Screw

| **Attributes** | **Proposed Devices**<br>**PUR NP Straight Abutment Slim 1.5mm & 3.0mm and .050" Hex Prosthetic Screw** | **Reference Predicate**<br>**Sterngold**<br>**PUR Straight Abutment 1.5mm and 3.0mm and 0.48" Prosthetic Screw (K151928)** |
|---|---|---|
| **Design** |  |  |
| **Material** | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI |
| **Surface** | Smooth | Smooth |
| **Ø Diameters (mm)** | 1.5mm, 3.0mm | 1.5mm, 3.0mm |
| **Hex** | .050" | **.**048" |
| **Sterilization** | Moist Heat | Moist Heat |
| **Single Use** | Yes | Yes |

## PUR NP Cover Screw

| **Attributes** | **Proposed Devices**<br>**PUR NP Cover Screw 3.2mm** | **Reference Predicate**<br>**Sterngold**<br>**PUR Cover Screw (K151928)** |
|---|---|---|
| **Design** |  |  |
| **Material** | Wrought Titanium 6AL-4V ELI | Wrought Titanium 6AL-4V ELI |
| **Surface** | Smooth | Smooth |
| **Ø Diameters (mm)** | 3.2mm | 3.5, 4.3, 5.0, 6.0mm |
| **Sterilization** | Gamma | Gamma |
| **Single Use** | Yes | Yes |

**7.0 Summary of Non-Clinical Performance Testing**

Non-clinical test data was used to support substantial equivalency.

Performance testing of the MOR 3.0mm, and PUR 3.2mm Implant Systems, MOR 2.1x18mm and MOR 2.4x18mm was implemented the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

**7.1 Biocompatibility**

A risk assessment was performed to identify biological hazards and evaluate estimated risks of known hazards. The evaluation of the biological safety of the proposed devices and their materials consisted of intended use, device characteristics, biological hazard identification, and exposure assessment. A biological evaluation was then performed in accordance with EN ISO 10993-1. The final device was considered during evaluation as well as materials, processes, physical characteristics and properties of finished device, intended use, contact type and duration.

The subject device was compared to the new device and the old submission biocompatibility was sufficient to support SE. There were no changes to material composition or manufacturing process.

**7.2 Surface Treatment Analysis**

MOR 3.0mm, and PUR 3.2mm Implant Systems, MOR 2.1x18mm and MOR 2.4x18mm are blasted with white aluminum oxide particles followed by acid etching. SEM and EDS analysis was performed on the blasted implant surface of a final device.

SEM photographs and surface analysis confirm that residue and contaminants from the blasting material were not present or detectable in any form and implant surface was homogeneous.

**7.3 Sterilization and Shelf-Life Validation**

MOR 3.0mm, and PUR 3.2mm Implant Systems, MOR 2.1x18mm and MOR 2.4x18mm are provided sterile and are sterilized using Cobalt 60 gamma radiation $VD_{max}^{25}$ method that has been validated to ensure a SAL of $10^{-6}$ per BS EN ISO 11137-1: 2015 and BS EN ISO 11137-2: 2015.

The Abutments, temporary Cap, prosthetic screw and drills are provided non-sterile and sterilized prior to use by the end user using moist heat sterilization. Validation was conducted according to ANSI/AAMI/ISO 17665-1: 2006 and 17665-2: 2009. The overkill method was used to develop a cycle (time and temperature) that would provide a Sterility Assurance Level (SAL) of $10^{-6}$. The devices were tested to a SAL of at least$10^{-6}$ using the biological indicator overkill method.

The MOR 3.0mm, and PUR 3.2mm Implant Systems, MOR 2.1x18mm and MOR 2.4x18mm are labeled sterile with a 5-year shelf life supported by validation performed on Sterngold's own devices. Validation testing using the Accelerated Aging method was conducted and results indicated a successful sterility; dye, burst and aerosol challenge tests showed that the packaging is able to maintain a sterile barrier for up to five (5) years. Shelf life validation was performed according to AAMI/ ANSI /ISO 11607-1: 2006/(R) 2010.

LAL testing was conducted as per the FDA Guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

**7.4 Torque Testing**

Testing consisted of a torque test, which simulates the intended use of the proposed devices. Each implant size was tested to determine how they would perform being inserted in different density test blocks by measuring their final insertion torque values. Very dense urethane foam blocks were used to place the implants in so as to attain high torque values to test for breakage.

All implants were placed without any breakage. The testing goal was to greatly exceed the torque that would be encountered clinically. It was observed that even at 60Ncm, the proposed implants performed successfully with no evidence of breakage. Torque testing and implant to abutment compatibility demonstrated conformance to design input and indications for use.

**8.0 Conclusion:**

The proposed devices have the same technological characteristics, performance specifications and intended use as of its predicates. Performance testing data and intended use supports a determination of substantial equivalence of the proposed devices to the predicate and the reference devices.