



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 6, 2015

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

Re: K151928
Trade/Device Name: PUR Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 29, 2015
Received: September 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,

Erin I. Keith -S

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): K151928

Device Name: PUR Implant System

Indications for Use:

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

The PUR Implant System is only intended for use with straight abutments. The PUR implant body is intended to be placed such 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: PUR 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: November 1, 2015

Device Generic Name: Dental endosseous implant system

Classification: 21 CFR 872.3640. Endosseous dental implant, Class II

Product Code: DZE, NHA

Predicate Devices:

The PUR 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.

- Zimmer Dental Implants (K061410) - **Primary Predicate**
- Screw Vent[®] and Tapered Screw-Vent[®] (K013227) - Reference Predicate
- Sterngold Acid Etch Dental Implant System (K023580) - Reference Predicate
- Implamed UCLA Abutments and Accessories (K933193) - Reference Predicate

Product Description:

The PUR is a self-tapping, double thread screw implant with a micro groove section, manufactured from Wrought Titanium 6AL-4V ELI. The implant surface is grit-blasted and 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 and 4.3 mm implants have a Narrow Platform (NP) prosthetic head. The 5.0 and 6.0 mm implants have a Regular Platform (RP) prosthetic head. The PUR implants are substantially equivalent to the Zimmer Tapered Screw-Vent[®] 3.5 mmD Platform and the 4.5 mmD Platform implant systems. 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.

This device uses straight abutments with no angles. Sterngold has SA Abutments (straight abutments) which are intended for multi-unit restorations. Sterngold also has UCLA abutments which are two-piece abutments composed of Wrought Titanium 6AL-4V ELI, conforming to ASTM F136-13 and Gold Alloy (64% gold, 22% palladium and 14.0% platinum). These UCLA abutments are intended for single and multiple unit use.

The PUR implant system is not intended to include any angled abutments or allow for any correction of angled implant placement.

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

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

Dimensional requirements for the finished abutment:

Angulation of final abutment: No angles
Minimum and Maximum Gingival Height: 1.5 - 3.0mm
Minimum abutment post height may be fabricated to: 4.0mm

Indications for Use:

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

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

Substantial Equivalence:

The proposed PUR 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. While the Indications for Use statements are not identical between the subject and referenced predicates, the difference in verbiage does not alter the intended use of the subject device. The subject and reference devices all provide oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Both the subject device and its primary predicate are intended for delayed loading as well as immediate loading when there is good primary stability and an appropriate occlusal load. Therefore, the differences noted between the subject and predicates Indications for Use verbiage do not render the subject device as not substantially equivalent to its referenced predicates. The intended use, basic design, fundamental operating principles, sterilization process, shelf life and bio-compatibility of the subject device are equivalent to the predicate devices.

Technological Characteristics:

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

The abutments for the subject device are the same or similar to the predicate devices, in terms of intended use, design and function. The materials, technology and processes used to produce the PUR 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 affect the substantial equivalence. See the comparison chart below for list of similarities and differences.

Performance Testing:

Non clinical Testing was performed following "Guidance for Industry and FDA Staff -Class II 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.

Surface analysis was conducted on the final device. SEM photographs confirm that all residue of blasting material had been removed from the treated implant surface, and the surface chemical analysis confirmed that no contaminants remained on the surface.

PUR Implants 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 PUR Implants. As a result, the PUR Implant System including abutments is substantial equivalent to its predicates.

Conclusion:

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

Property	Subject Device K151928	Predicate Device K061410	Predicate Device K013227	Predicate Device K023580	Predicate Device K933193
Intended Use	The PUR 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 PUR Implant is intended for delayed loading. It is also indicated for immediate loading with good primary stability and appropriate occlusal loading. The PUR Implant System is only intended for use with straight abutments. The PUR implant body is intended to be placed such no angle correction is necessary.	For use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.	For use in edentulous mandible and maxilla for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework or as a freestanding single tooth replacement.	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.	The UCLA Abutments are indicated for use when fabricating bridges and single tooth restorations and attaching directly to the implant.
Implant Design	Threaded, Root-form implant	Threaded, Root-form implant	Threaded, Root-form implant	Threaded, Root-form implant	N/A
Implant Shape	Cylinder	Cylinder	Cylinder	Cylinder	N/A
Implant Body Diameter	3.5mm, 4.3mm, 5.0mm, 6.0mm	3.7mm, 4.1mm, 4.7mm, 6.0mm	3.7mm, 4.1mm, 4.7mm, 6.0mm	3.3mm, 4.0mm, 5.0mm	N/A
Implant Length	8mm, 10mm, 12mm, 14mm	10.0mm, 11.5mm, 13.0mm, 16.0mm	8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm	8.5mm, 10.0mm, 11.5mm, 13.0mm, 15.0mm	N/A
Outer Thread	0.136 - 0.140"	0.136 - 0.140"	0.136 - 0.140"	0.136 - 0.140"	N/A
Surface	Blasted with aluminum oxide particles and acid etched	Roughened - HA blasted	Roughened - HA blasted	Blasted with aluminum oxide particles and acid etched	Titanium
Hex Connection	Internal Connection	Internal Connection	Internal Connection	External Connection	N/A
Internal Thread	0.0730"	0.0730"	0.0730"	0.0730"	N/A
Prosthetic Platform	Hex	Hex	Hex	Hex	N/A
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
Manufacturing Process	Machining	Machining	Machining	Machining	Machining
Implant Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	N/A
Abutment Material	Wrought Titanium 6AL-4V ELI Gold Alloy (64% gold, 22% palladium and 14.0% platinum)	Wrought Titanium 6AL-4V ELI Gold Alloy	Wrought Titanium 6AL-4V ELI Gold Alloy	Wrought Titanium 6AL-4V ELI	Wrought Titanium 6AL-4V ELI Gold Alloy (64% gold, 22% Machining
Manufacturing Process	Machining	Machining	Machining	Machining	Machining
Abutment Sterilization	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)
Abutment Angulation	No Angles	No Angles	No Angles	No Angles	No Angles