DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 24, 2014

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

Re: K142407
Trade/Device Name: Straight Stud Attachment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 25, 2014
Received: November 26, 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 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" (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 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.
Division 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): K142407

Device Name: **Straight Stud Attachment**

Indications for Use:

The Straight Stud Attachment is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The attachment screws into SFI Abutments which are screwed into endosseous implants.

The Straight Stud Attachment is compatible with all Sterngold SFI 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 Subparts D) AND/OR Over-the -Counter Use ____ (21 CFR 807 Subpart D)

K142407

510(k) Summary

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 25, 2014

Trade Name: Straight Stud Attachment

Common Name: Dental Attachment

Classification Name: Endosseous dental implant abutment
21 CFR 872.3630

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

Product Code: NHA

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Trade Name	510(k) No.	Manufacturer
SFI Bar® Implant Abutments	K130183 and K132814	Sterngold Dental, LLC
SFI Anchor	K130618	Cendres & Metaux, SA
Locator Implant Anchor	K994257	Zest Anchors, Inc.

Description of Device:
The Straight Stud Attachment is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The attachment screws into SFI Abutments which are screwed into endosseous implants.
The attachment consists of a modified ball, which screws into an SFI Abutment and a retaining female, which is processed into the denture. The retaining female engages the outside of the ball shape and allows retention of the prosthesis to the denture.

Sterngold SFI abutments are compatible with several implant systems that have been previously cleared under K130183 and K132814 - SFI Bar® Implant Abutments.

The Straight Stud Attachment is a straight attachment and is not intended for angulation of divergent implants. It has a 0.048" hex for tightening to the SFI abutment.

Intended Use of the Device:
The Straight Stud Attachment is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The attachment screws into SFI Abutments which are screwed into endosseous implants.
The Straight Stud Attachment is compatible with all Sterngold SFI Abutments.

Summary Technological Characteristics:
The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices - titanium alloy, polyurethane (brown, green, yellow, black) were also used in legally marketed predicate devices.
A Failure Mode and Effects Analysis (FMEA) was performed to ensure safety of device.

Substantial Equivalence:
The proposed Straight Stud Attachment is substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.
To ensure compatibility, the Straight Stud Attachment was designed, developed, and manufactured according to manufacturer's specifications and controlled procedures and validated following a validation protocol in accordance with Design Control requirements per FDA CFR820.30.

Non-Clinical Performance Data:
The specifications for a reliable connection between the Straight Stud Attachment and the SFI implant abutments were developed by analyzing the SFI Abutment specifications. Non-clinical test data was used to support the substantial equivalency. Clinical testing was not necessary. Non-clinical testing consisted of analysis of the SFI abutment top portion (head) and Stud Attachment screw section, dimensional verification against drawing, and fit checks of attachment to SFI abutment on several samples to ensure connection was reliable and functional.
Retention force testing was conducted to ensure level of retention was acceptable.
Evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments".
Testing has shown that the Straight Stud Attachment is equivalent in performance characteristics to the predicate devices.

Conclusion as to Substantial Equivalence:
Based on the technological characteristics, non-clinical functional testing and comparison of indications for use, it can be concluded that the Straight Stud Attachment is substantially equivalent to the predicate devices.