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

June 11, 2015

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

Re: K150250
Trade/Device Name: *SternSnap* Angled Attachment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 4, 2015
Received: May 6, 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,

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): K150250

Device Name: ***SternSnap* Angled Attachment**

Indications for Use:

The *SternSnap* Angled 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 *SternSnap* Angled Attachment is compatible with 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)

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: June 3, 2015

Trade Name: *SternSnap* Angled Attachment

Common Name: Dental Attachment

Classification Name: Endosseous Dental Implant Abutment

Classification: 21 CFR 872.3630, Class II

Product Code: NHA

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

Trade Name	**510(k) No.**	**Manufacturer**	**Manufacturer**
Straight Stud Attachment	K142407	Sterngold Dental, LLC	Primary Predicate
SFI Bar® Implant Abutments	K130183 and K132814	Sterngold Dental, LLC	Reference Predicate
SFI Anchor	K130618	Cendres & Metaux, SA	Reference Predicate
SFI Bar	K131526	Cendres & Metaux, SA	Reference Predicate

Description of Device:
The *SternSnap*Angled 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. An appropriate height Sterngold SFI Abutment is screwed into an endosseous implant. A *SternSnap* Angled Attachment is screwed into the SFI Abutment. The *SternSnap* Angled Attachment can be manually pivoted on the hemispherical occlusal of the SFI Abutment until alignment is achieved. A retaining cap is processed into the denture. The retention cap engages the outside of the modified ball shape and allows retention of the prosthesis to the denture.

The proposed device is intended for angulation of divergent implants.
The *SternSnap* Angled Attachment can be pivoted from a central, 0 degree, position up to and including 17 degrees. It can also be rotated through 360 degrees. Therefore, two *SternSnap* Attachments can align two implants that are up to and including 34˚ out of parallel.
The *SternSnap* Angled Attachment is only to be used with Sterngold SFI Abutments.

The SFI abutments are compatible with several implant systems and have been previously cleared under K130183 and K132184 - SFI Bar® Implant Abutments.

Intended Use of the Device:
The *SternSnap* Angled 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 *SternSnap* Angled Attachment is compatible with 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.

Attributes	Proposed Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	Reference Predicate Device
	***SternSnap* Angled Attachment Sterngold Dental, LLC**	**Straight Stud Attachment Sterngold Dental, LLC K142407**	**SFI Implant Abutments Sterngold Dental, LLC K130183, K132814**	**SFI Anchor Cendres & Metaux, SA K130618**	**SFI Bar Cendres & Metaux, SA K131526**
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Titanium
Manufacturing	Machined	Machined	Machined	Machined	Machined
Retentive Force	Up to 4.0 lb (17.8 N)	Up to 4.0 lb (17.8 N)	Up to 4.5 lb (20 N)	Up to 3.93 lb (17.5 N)	N/A
Operating Principle	Screw fixation to SFI Abutment. Connecting principle to overdenture: Retentive system	Screw fixation to SFI Abutment. Connecting principle to overdenture: Retentive system	Screw fixation to Implant. Connecting principle to overdenture: Retentive system	Screw fixation to Implant. Connecting principle to overdenture: Retentive system	Screw fixation to Implant. Connecting principle to overdenture: Retentive system
Indications for Use	Intended for the fixation of dental prostheses to corresponding dental implants.	Intended for the fixation of dental prostheses to corresponding dental implants.	Intended for the fixation of dental prostheses to corresponding dental implants.	Intended for the fixation of dental prostheses to corresponding dental implants.	Intended to provide support for the fixation of dental prostheses to corresponding dental implants.

Non-Clinical Performance Data:
The specifications for a reliable connection between the *SternSnap* Angled 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 *SternSnap* Angled Attachment screw section, dimensional verification against drawing, and fit checks of angled attachment to SFI abutment to ensure connection was reliable and functional.

Review of fatigue testing data performed on the Angled SFI Bar by Cendres & Metaux showed the device being tested "with an angle of 30˚ to the implant axes". The SFI abutments support the pivoting ball component of the SFI Bar. This demonstrates that the proposed device is substantial equivalent to its predicates.

Cyclic Load testing was conducted to ensure prosthetic screw would remain tightened to the initial torque after 10,000 cycles and angled attachment would still be in their original orientation after 1,000 cycles. 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 *SternSnap* Angled Attachment is equivalent in performance characteristics to the predicate devices.

Substantial Equivalence: The summary of technological characteristics and performance testing indicate that the device is substantially equivalent to its predicate devices.
The intended use and technological characteristics are the same as the Straight Stud Attachment previously cleared under K142407.