K132914

510(k) Summary

FEB 2 5 2014

Sponsor: Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

Contact: Maria Rao, QA/RA Director
Ph: 508-226-5660 ext 1206

Trade Name: SFI Bar® Implant Abutments

Common Name: Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

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

Product Code: NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):
Predicate Device(s): K130183, K102382.

K130183	SFI Bar® Implant Abutments for 7 Platforms
K102382	SFI Bar® Implant Adapter Straumann, SFI Bar® Implant Adapter Neos

Description of Device:
Device Description: The SFI Bar® Implant Abutments provide the connection between compatible dental implant systems for the fixation of removable overdentures. The SFI Bar® Implant Abutments consist of an abutment, which is attached to a stress free bar for the fixation of removable overdentures. The implant abutment is screwed into the dental abutment.
The implant abutments fit Straumann Bone Level RP, Straumann Bone Level NP, Ankylos, Nobel 5mm Trilobe, Nobel Conical RP, Nobel Conical NP, Astra 4.5/5.0, Astra 3.5/4.0, Zimmer TSV 5.7mm.
See table 1 for platform compatibility.

There are nine (9) different platforms and each platform is compatible with one or more implant types. The platforms of the abutments are [BD], [BE], [AE], [AN], [AP], [AY], [AJ], [AK], [BF]. Table 1 indicates which implants are compatible with these platforms. The difference between each platform is the internal connection with the specific implant.

The devices are supplied non-sterile, therefore there is no shelf life.

Abutment Insertion
Choose the abutment with the proper cuff height that fits on the existing implant. Abutment platforms should be 1 to 2 mm above the gingival level and approximately parallel to the occlusal plane. However, to allow the subsequent placement of the sections of SFI-Bar® on top of these abutments so that the bars are approximately parallel to the occlusal plane, it may be necessary to choose some abutments with different heights. Abutments are screwed into each implant.

Intended Use of the Device:
The SFI-Bar® Implant Abutments are indicated to be used with dental implants as a prosthetic framework to support and /or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

The SFI-Bar® Implant Abutments are compatible with the following implant systems:

Implant Brand	Model
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

Summary Technological Characteristics:
The proposed implant abutments are 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.

The material of the implant abutments conform to ASTM F136, Wrought Titanium 6 Aluminum-4 Vanadium ELI Alloy.

Comparison/Compatibility
Substantial Equivalence:
The proposed implant abutments are 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 following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.
Table 2 summarizes the substantial equivalence comparison to the predicate devices.

Performance Data:

Application and functional testing have been conducted to evaluate the performance characteristics of the SFI Bar® Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the SFI Bar® Implant Abutments included in this application are equivalent in performance characteristics to the predicate SFI Bar®. The acceptance criteria were met.

Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." Torque tests, application and functional tests have been carried out.

The summary of technological characteristics as well as application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

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

February 25, 2014

Sterngold Dental LLC
Ms. Maria Rao
Quality Assurance Director
23 Frank Mossberg Drive
Attleboro, MA 02703

Re: K132814
Trade/Device Name: SFI Bar Implant Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 21, 2014
Received: January 22, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

SECTION 2

510(k) Number (if known): K132814

Device Name: **SFI Bar® Abutments for 9 Implant Platforms**

Indications for Use:

The SFI-Bar® Implant Abutments are indicated to be used with dental implants as a prosthetic framework to support and /or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

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Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2014.02.24
10:28:46 -05'00'

Prescription Use __X__ AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subparts D) (21 CFR 807 Subpart D)