SEP 12 2011

K111390

Attachment: 510(k) Summary

Applicant's Name and Address

Submitter: CENDRES+METAUX SA
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Contact Person: Tanja Bongni
Consultant Regulatory Affairs

Date of Submission: May 09, 2011

Name of the Device

Trade Name: SFI-Bar®
Common Name: Abutment, Dental, Endosseous implants
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: 21 CFR 872.3630

Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

Predicate Device(s): K073628, K083876, K102382

Description of the Device

Device Description: The SFI-Bar® provides the connection between compatible dental implant systems for the fixation of removable overdentures. The SFI-Bar® consists of an implant adapter (abutment) and a stress-free bar for the fixation of removable overdentures. The implant adapter is screwed into the dental implant.

The implant adapter (abutment) fit the Thommen SPI® Element Platform Ø 4.0 mm / the Neoss ProActive Implant Ø 3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm and the Straumann dental implants / ITI Dental Implant System® Standard Ø 4.1 and Ø 4.8 mm / Standard Plus Ø 4.1 mm and Ø 4.8 mm / Tapered Effect Ø 4.1 and Ø 4.8 mm and Regular Neck (RN) Ø 4.8 mm.

The implants (min. 2) in the mandible can be fitted with the SFI-Bar® immediately after implantation, provided the following criteria are met:

- Implant manufacturers permit immediate loading in their system.
- No necessity for simultaneous guided bone regeneration; implants surrounded on all sides by local bone.
- Implant insertion torque min. 35 Ncm.
- All parts are sterilized or disinfected.
- Pull-of strength during osseointegration <20 N.

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Intended Use of the Device:

The SFI-Bar® is intended to be used with the implant manufacturer's (TABLE A) implant to provide support for fixation of overdentures.

TABLE A Compatible Commercial Implant Manufacturers:

Implant Company	Implant System	Implant Platform Diameter
Thommen Medical	SPI® Element Platform	4.0 mm
Neoss	Neoss ProActive Implant	3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm
Institut Straumann	ITI Dental Implant System®	Standard 4.1 and 4.8 mm / Standard Plus 4.1 and 4.8 mm / Tapered Effect 4.1 and 4.8 mm / Regular Neck (RN) 4.8 mm

Summary Technological Characteristics:

The proposed labelling change to the SFI-Bar® 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 device.

The material of the implant adapters conform to ASTM F 136, Wrought Titanium-6Aluminium-4Vanadium ELI Alloy for Surgical Implant applications (UNS R 56401). The parts for the SFI-Bar® System are manufactured from wires.

Comparison /Compatibility Substantially Equivalence:

The proposed implant adapters 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 device.

To ensure compatibility the following process was carried out:
The implant adapters are developed and manufactured in close cooperation with the implant companies (see TABLE A, column "Implant Company").
There are Quality Agreements between CENDRES+METAUX and the implant companies in place. Those agreements handle among other things the Design Control, Change Control, Complaint Handling and Post Market Surveillance.

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TABLE B summarizes the substantial equivalence comparison to the predicate device:

TABLE B Substantial Equivalence Comparison to Predicate Devices:

Attribute	Candidates	Predicate Device	Predicate Device
	SFI-Bar®	SFI-Bar®	RN synOcta®
510(k) Number		K083876, K102382	K073628
Design / construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Platform compatibility	ITI Dental Implant System®: Standard Ø 4.1 mm and Ø 4.8 mm / Standard Plus Ø 4.1 mm and Ø 4.8 mm / Tapered Effect Ø 4.1 mm and Ø 4.8 mm / Regular Neck (RN) Ø 4.8 mm Neoss ProActive Implant: Ø 3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm Thommen Implant System: SPI® Element Platform Ø 4.0 mm	ITI Dental Implant System®: Standard Ø 4.1 mm and Ø 4.8 mm / Standard Plus Ø 4.1 mm and Ø 4.8 mm / Tapered Effect Ø 4.1 mm and Ø 4.8 mm / Regular Neck (RN) Ø 4.8 mm Neoss ProActive Implant: Ø 3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm Thommen Implant System: SPI® Element Platform Ø 4.0 mm	ITI Dental Implant System®: Standard Ø 4.8 mm RN and Ø 6.5 mm WN / Standard Plus Ø 4.8 mm and Ø 6.5 mm WN / Tapered Effect Ø 4.8 mm and Ø 6.5 mm WN
Device Material	Wrought Titanium-6Aluminium-4Vanadium ELI Alloy for Surgical Implant applications	Wrought Titanium-6Aluminium-4Vanadium ELI Alloy for Surgical Implant applications	Titanium abutment, Ceramicor sleeve
Manufacturer	CENDRES+METAUX SA	CENDRES+METAUX SA	Institut Straumann AG
Indication for Use	The SFI-Bar® is intended to be used with the implant manufacturer's (see TABLE A) implant to provide support for fixation of overdentures.	The SFI-Bar® is intended to be used with the implant manufacturer's (see TABLE A) implant to provide support for fixation of overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.
Operating principle / Basic Design	Impression taking: optional, preassembled (plug-in connection). Abutment implant connection: screw fixation. Connecting principle to overdenture: retentive system. Bar fixation on implant: screwed. Function: stabilization and primary splinting of implants. Countering forces that would dislodge the	Impression taking: optional, preassembled (plug-in connection). Abutment implant connection: screw fixation. Connecting principle to overdenture: retentive system. Bar fixation on implant: screwed. Function: stabilization and primary splinting of implants. Countering forces that would dislodge the	Impression taking: required. Abutment Implant connection: Screw fixation. Bar connection: soldered. Connecting principle to overdenture: retentive system. Bar fixation on implant: screwed. Countering forces that would dislodge the

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Attribute	Candidates	Predicate Device	Predicate Device
	denture, distribution of shear forces, resilience compensation. Cleaning procedures for patient: common procedure for oral hygiene. Patient handling: common cleaning and insertion of denture.	denture, distribution of shear forces, resilience compensation. Cleaning procedures for patient: common procedure for oral hygiene. Patient handling: common cleaning and insertion of denture.	denture, distribution of shear forces, resilience compensation. Cleaning procedures for patient: common procedure for oral hygiene.
Shelf life	95% after 10 years	95% after 10 years	95% after 10 years
Packaging, materials and processes	Produced on process orientated CNC machines. The last step is a validated cleaning process (same processes). Packaging: dental blister, non-sterile.	Produced on process orientated CNC machines. The last step is a validated cleaning process (same processes). Packaging: dental blister, non-sterile.	Produced on process oriented CNC machines. The last step is a validated cleaning process (same process). Packaging: non-sterile.
Abutment / implant adapter used in context with the immediate loading.	Yes (this submission).	No.	Yes. Abutment cleared for immediate loading.

Performance Data:

Validation of Sterilization for the metallic components, evaluation of the intended manual disinfection procedure with SFI-Bar® Retention inserts G, application and functional testing based on literature research have been conducted to evaluate the performance characteristics of the SFI-Bar®. The test methods used were the same as in the predicate device. Testing has shown that the SFI-Bar® is 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. Non-clinical testing consisted of analysis of platforms to identify worst-case test samples. Fatigue testing was not done as the basic design is the same than the predicate device. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." Application and functional tests are based on the predicate device and literature research.
The summary of technological characteristics 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
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Silver Spring, MD 20993-0002

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SEP 12 2011

Re: K111390
Trade/Device Name: SFI-Bar®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 23, 2011
Received: August 29, 2011

Dear Ms. Bongni:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment: Indications for Use Statement

Device Name: SFI-Bar®

Indications for Use:
The SFI-Bar® is intended to be used with the implant manufacturer's implant (TABLE a) to provide support for fixation of overentures.

Implant Company	Implant System	Implant Platform Diameter
Institut Straumann	ITI Dental Implant System®	Standard 4.1 and 4.8 mm / Standard Plus 4.1 and 4.8 mm / Tapered Effect 4.1 and 4.8 / Regular Neck (RN) 4.8 mm
Thommen Medical	SPI® Element Platform	4.0 mm
Neoss	Neoss ProActive Implant	3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm

TABLE a Compatible Commercial Implant Manufacturers

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Susan Runner

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111390

Prescription Use __x___ OR Over-The-Counter Use _____