510(k) Summary

Applicant's Name and Address

Submitter: Cendres+Métaux SA
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Contact Person: Tanja Bongni
Regulatory Affairs Manager

Date of Submission: February 24, 2014

Name of the Device

Trade Names:	SFI-Anchor® D20, SFI-Anchor® CD20
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Product Code:	NHA
Device Class:	II

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

Trade Name	510(k) no
SFI-Bar®	K111390, K102382, K083876
Locator Implant Anchor	K994257
P.004 RC/NC Bar and Bridge Abutments Line	K080239

Figure 1 Predicate Devices

Description of the Device

Device Description:

The SFI-Anchor® D20 is an endosseous dental implant abutment for the fixation of (dental) prostheses to the following ITI Dental Implant System® / Straumann® Dental Implant Systems:
Standard Ø 4.1 mm Regular Neck (RN) / Standard Ø 4.8 mm Regular Neck (RN) / Standard Plus Ø 4.1 mm Regular Neck (RN) / Standard Plus Ø 4.8 mm Regular Neck (RN) / Tapered Effect Ø 4.1 mm Regular Neck (RN) / Bone Level Ø 4.1 mm, Regular CrossFit® (RC) / Bone Level Ø 4.8 mm, Regular CrossFit® (RC).
The SFI-Anchor® CD 20 is intended as an additional retaining element on dental bars. The SFI-Anchor® D20 are straight abutments with gingival heights ranging from 1mm to 5 mm. The SFI-Anchor® CD 20 is a straight bar attachment. The SFI-Anchor® Housing and the SFI-Anchor® Retention Inserts can correct for up to 10° of divergence (20° of divergence between two implants).

The SFI-Anchor® is offered in a diameter 4.8 mm. The SFI-Anchor® D20 is connected to the corresponding implants via a mating screw thread and interface geometry. The SFI-Anchor® CD20 is directly screwed on a dental bar construct. The SFI-Anchor® Housing is cemented in the dental prostheses. The SFI-Anchor® Housing, along with an SFI-Anchor® Retention Insert, allow connection of the prosthesis to the abutment / bar attachment by retention-grip.

The abutments / bar attachment are machined from Titanium Alloy conforming to ASTM F-136. Other SFI-Anchor® key functional parts are made out of Elitor® (conforming to standard ISO 22674) and of Pekkton® conforming to standard ASTM D3418, ASTM D638 and ASTM D790.

Indications for Use:
The SFI-Anchor® D20 is intended for the fixation of (dental) prostheses to corresponding dental implants.

The compatible implant systems are specified in Table 1 below.

Implant Manufacturer: Institut Straumann Implant System: ITI Dental Implant System® respectively Straumann® Dental Implant System Implant line name(s): see below	
-Standard Ø 4.1 mm Regular Neck (RN)	-Standard Ø 4.8 mm Regular Neck (RN)
-Standard Plus Ø 4.1 mm Regular Neck (RN)	-Standard Plus Ø 4.8 mm Regular Neck (RN)
-Tapered Effect Ø 4.1 mm Regular Neck (RN)	-Bone Level Ø 4.1 mm, Regular CrossFit® (RC)
-Bone Level Ø 4.8 mm, Regular CrossFit® (RC)	

Table 1 Compatible Implant Systems

The SFI-Anchor® CD20 is intended as an additional retaining element on CAD / CAM milled dental bars.

Summary Technological Characteristics
The following Figure 2 describes similarities and differences between the subject devices and legally cleared predicates:

	Candidates:		Predicate Devices			Comparison
	SFI-Anchor® D20	SFI-Anchor® CD20	SFI-Bar®	Locator Implant Anchor	P.004 RC/NC Bar and Bridge Abutments Line	
Platform compatibility (implant)	Refer to Table 1	N/A	Regular Neck (RN) (and others)	---	Regular CrossFit® (RC) (and others)	Same implant platforms than SFI-Bar® and P.004.
Basic Design of the Abutment / Element	Straight, gingival heights ranging from 1mm to 5 mm.	Straight	Straight, gingival heights ranging from 1 to 6.	Straight, gingival heights ranging from 1 to 5.	Straight (and others)	Comparable to Predicates
Retentive force	Up to 17.5 N	Up to 17.5 N	Up to 14 N	Up to 5.0 pounds (22.25 N)		Comparable to SFI-Bar® and Locator.
Divergence Compensation by Housing and Retention insert	Up to 10° per implant (20° between 2 implants)	Up to 10° per implant (20° between 2 implants)				

Figure 2 Comparison with Predicate Devices

The following materials with permanent patient contact are incorporated into key functional elements: Titanium; Elitor®; Pekkton® (blue, red, yellow, green). Similar material was used in the legally marketed predicate devices.
The proposed devices are similar in terms of design, angulations, sizes, indications for use and incorporate the same technological characteristics as the predicate devices.
In order to assure safety of the SFI-Anchor® a failure mode, effect and criticality analysis has been performed.

Non-Clinical Performance Data

The specifications for a reliable connection between the dental implant and the SFI-Anchor® are developed in close cooperation with the dental implant manufacturer. To ensure compatibility today and in future there is a Quality Agreement between Cendres+Métaux SA and the Institut Straumann AG in place. This Quality Agreement handles among other things the Design Control process and Vigilance.
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. Retention force testing and simulated use testing were done. Furthermore, the evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Conclusion as to Substantial Equivalence

Based on the comparison of the indications for use, the technological characteristics and the non-clinical testing it can be concluded that the SFI-Anchor® is substantially equivalent to 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

March 3, 2014

Cendres+Metaux SA
Ms. Tanja Bongni
Regulatory Affairs Manager
Rue de Boujean 122
2501 Biel/Bienne
SWITZERLAND

Re: K130618
Trade/Device Name: SFI-Anchor® D20, SFI-Anchor® CD20
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 29, 2014
Received: January 30, 2014

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 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,

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

510(k) Number (if known): K130618

Device Names: SFI-Anchor® D20, SFI-Anchor® CD 20

Indications for Use:

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The compatible implant systems are specified in Table 1 below.

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-Bone Level Ø 4.8 mm, Regular CrossFit® (RC)	

Table 1 Compatible Implant Systems

The SFI-Anchor® CD20 is intended as an additional retaining element on CAD / CAM milled dental bars.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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