K101465

DEC 13 2010

510(k) SUMMARY

Submitter

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Date: ..... November 23, 2010

Name of Device

Proprietary Name: ..... Straumann® CARES® Screw-Retained Bridge
Straumann® CARES® Dolder® Bar

Classification Name ..... Endosseous Dental Implant Abutment

Common Name: ..... Implant Bridge

Regulation Number and Product Code

Regulation Number: ..... 21 C.F.R § 872.3630

Product Code: ..... 76 NHA

K101465

Predicate Devices

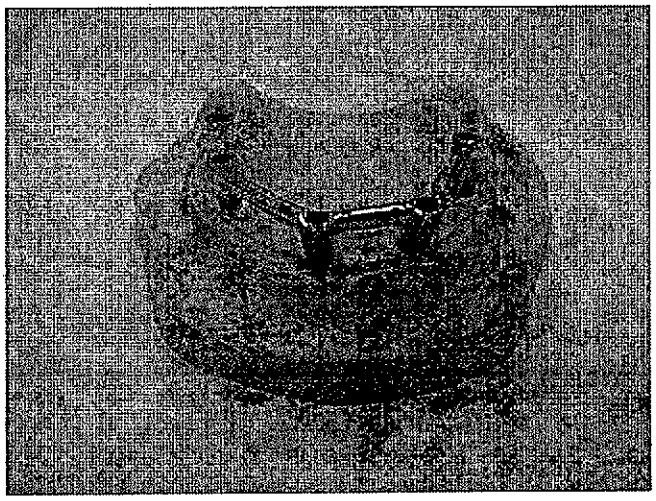
Procera Implant Bridge Overdenture K090069

Procera Implant Bridge K041236

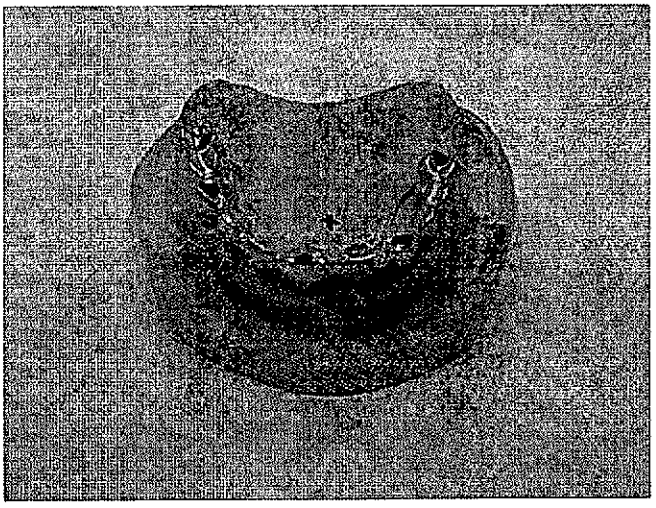
ETKON ES1, MODEL 019.0001, ETKON VISUAL, STRAUMANN CADCAM ABUTMENT K093113

Device Description

Straumann® CARES® Screw-Retained Bridges and Straumann® CARES® Dolder® Bars are dental restorative devices intended to be attached directly to dental implants by basel screws. The Straumann CARES Screw-Retained Bridge and Straumann CARES Dolder Bar are designed with implant interfaces comparable to a single tooth abutment which are attached to a Straumann implant RN (Regular Neck) Ø 4.8 mm and WN (Wide Neck) Ø 6.5 mm.



Example screw retained bar to be mounted on 5 dental implants (may be fixed on 2 to 10 implants)



Example screw retained bridge to be mounted on 5 dental implants (may be fixed on 2 to 16 implants)

The implant positions and oral situation are recognized by a scan of a dental master model with implant analogs and scanbodies. Based on the scan data, the dental technician selects the proper implant interfaces and designs the bar or bridge according to a dentist's prescription.

Once the Straumann CARES Screw-Retained Bridge or Straumann CARES Dolder Bar is designed, the digital dataset is sent to Straumann CADCAM by an internet connection where the bridge or bar is milled from a cobalt-chromium-based blank.

Straumann CARES Screw-Retained Bridges and Straumann CARES Dolder Bars allow for individual customization regarding function and esthetics. They attach directly to Straumann dental implants. The device is intended to be finished into a bridge or overdenture using standard dental laboratory techniques and materials. The devices are CAD-derived, CAM-produced and have a scanner as its data source.

The milling blanks used for the manufacture of Straumann CARES Screw-Retained Bridge and Straumann CARES Dolder Bar are manufactured from a cobalt chromium base metal alloy, which has been tested and

found biocompatible for its intended use. The cobalt chromium alloy meets the physical and mechanical requirements of ISO 22674, Dentistry - Metallic materials for fixed and removable restorations and appliances and ISO 9693, Metal-ceramic dental restorative systems.

Intended Use

The Straumann® CARES® Screw-Retained Bridge and Straumann® CARES® Dolder® Bar indicated for use as bars and bridges that attach to dental implants (Straumann RN (Regular Neck) Ø 4.8 mm and WN (Wide Neck) Ø 6.5 mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The Straumann CARES Screw-Retained Bridge can be designed for specific patient sizes and spans that are attached to 2 to 16 implants.

The Straumann CARES Dolder Bar can be designed for specific patient sizes and spans that are attached to 2 to 10 implants.

Technical Comparison to the Predicate Device

The Straumann CARES Screw-Retained Bridges and Straumann CARES Dolder Bars are equivalent in design and materials to the predicate device.

Table 1 compares the Straumann CARES Screw-Retained Bridges and Straumann CARES Dolder Bars to the predicate devices:

Table 1

Characteristic	**Straumann CARES® Screw-Retained Bridge Straumann CARES Dolder® Bar**	**Procera Implant Bridge K041236, K090069**
Indications for Use	Indicated for use as a screw retained bridge or bar framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	Same
Intended Use	Intended to be finished into a bridge or overdenture using standard dental laboratory techniques and materials.	Same
Connection Type	Screw retained dental restorations	Same
Connection Level	Dental implant	Same
Implant Interface Type	Straumann® RN (Regular Neck) Ø 4.8 mm and WN (Wide Neck) Ø 6.5 mm	Procera and Straumann (RN (Regular Neck) Ø 4.8 mm and WN (Wide Neck) Ø 6.5 mm) implant interface type
Design Parameters	3D scan and CAD	Same
Manufacturing Method	CADCAM milling from milling blanks	Same
Material (bar and bridge)	chromium/cobalt dental alloy	titanium (K041236) titanium, titanium/vanadium alloy, or chromium/cobalt alloy (K090069)
Finishing Method	Bridge: intended to be finished into a bridge by application of a veneering porcelain layer. Bar: intended to be finished into overdenture using standard dental laboratory techniques and materials.	Same

Cobalt/chromium alloys are widely used in dentistry as non-precious dental alloy for cast and CADCAM fabrication of cementable crowns and

bridges. Such alloys are regulated by 21CFR872.3710, product code EJH and are exempt from 510(k) requirements.

Non-Clinical Testing

Table 2 summarizes the metallic material properties of the Straumann CARES Screw-Retained Bridge and Dolder Bar.

Table 2

Property	Unit	Acceptance criteria with and without thermal treatment	Conclusion
Color	na[3]	Silver gray	passed
Density	g/cm^3	8.3	passed
Solubility in water	mg/l	insoluble	passed
Proof strength $R_{p0.2}$	MPa	> 360	passed
Vickers hardness	HV10	260	na
Elongation after fracture	%	> 2.0	passed
CTE (25-500°C)	10^{-6} K^{-1}	14.4	na
Solidus	°C	1320	na
Liquidus	°C	1420	na

[3] na is a notation for not applicable

K101465

Table 3 summaries the ceramic bonding properties of the Straumann CARES Screw-Retained Bridge and Dolder Bar.

Table 3

Veneering porcelain	**Debonding/crack-initiation strength τ_b [MPa]**	**Conclusion**
	Acceptance criterion	
Initial MC (GC)	> 25 MPa	passed
IPS InLine (Ivoclar Vivadent)	> 25 MPa	passed
HeraCeram (Heraeus Kulzer)	> 25 MPa	passed
VM13 (Vita Zahnfabrik)	> 25 MPa	passed

Table 4 summaries the biocompatibility testing performed on the Straumann CARES Screw-Retained Bridge and Dolder Bar.

Table 4

Test Method	**Biocompatibility Acceptance criteria**	**Results**
Cytotoxicity of extract	< 30 %	passed
Organic leachables qualitative	na[4]	na
Leachables quantitative	na	na

[4] na is a notation for not applicable

Table 5 summaries the static corrosion testing performed on the Straumann CARES Screw-Retained Bridge and Dolder Bar.

Table 5

Composite Material	Units	Acceptance Criterion	Results
Cobalt (Co)	$\mu g/cm^2$	≤ 100	passed
Chromium (Cr)	$\mu g/cm^2$	≤ 100	passed
Aluminum (Al)	$\mu g/cm^2$	≤ 100	passed
Titanium (Ti)	$\mu g/cm^2$	≤ 100	passed
Niobium (Nb)	$\mu g/cm^2$	≤ 100	passed
Tungsten (W)	$\mu g/cm^2$	≤ 100	passed
Silicon (Si)	$\mu g/cm^2$	≤ 100	passed
Manganese (Mn)	$\mu g/cm^2$	≤ 100	passed
Iron (Fe)	$\mu g/cm^2$	≤ 100	passed
Beryllium (Be)	$\mu g/cm^2$	≤ 100	passed
Cadmium (Cd)	$\mu g/cm^2$	≤ 100	passed

Table 6 summarizes the dynamic fatigue testing performed on the Straumann CARES Screw-Retained Bridge and Dolder Bar.

Table 6

Composite Material	Results
Minimal body testing (Connection testing)	passed
Free hanging bridge (Connector testing)	passed
Free end pontic bridge (Connector testing)	passed

Validation of the CARES Visual CAD software provides evidence that design parameters for the Straumann CARES Screw-Retained Bridges and Straumann CARES Dolder Bars have met their pre-determined acceptance criteria and that dental restorations meeting their design specifications can be manufactured by Straumann CAM milling devices

Conclusion

Non-clinical testing presented in this 510(k) demonstrate that the Straumann CARES Screw-Retained Bridge and Straumann CARES Dolder® Bar met predefined acceptance criteria and successfully passed verification and validation testing. The information presented in this 510(k) demonstrated that the Straumann CARES Screw-Retained Bridge and Straumann CARES Dolder® Bar are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Institut Straumann AG
C/O Ms. Janet Kay
Regulatory and Clinical Affairs Director
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

DEC 13 2010

Re: K101465
Trade/Device Name: Straumann® CARES® Screw-retained Bridge
Straumann® CARES® Dolder Bar
Regulation Number: 21 CFR. 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 6, 2010
Received: December 7, 2010

Dear Ms. Kay:

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,

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

Indications for Use

DEC 1 3 2010

510(k) Number (if known): K101465

Device Name: Straumann® CARES® Screw-retained Bridge
Straumann® CARES® Dolder® Bar

Indications for Use:

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The Straumann® CARES® Screw-retained Bridge is available in different sizes and spans and can be fitted on 2 to 16 implants.

The Straumann® CARES® Dolder® Bar is available in different sizes and spans and can be fitted on 2 to 10 implant.

Prescription Use__X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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