5 510(k) Summary of Safety and Effectiveness

DEC 2 1 2012

5.1 Applicant's Name and Address

Institut Straumann AG
Peter Merian-Weg 12
CH-4052 Basel
Switzerland

Telephone Number: +41 61 965 1482
Fax Number: +41 61 965 1102
Contact Person: Andreas Petermann, Director, Corporate Regulatory Affairs

5.2 Date of Submission

March 16, 2012

5.3 Name of the Device

Trade Name: Straumann® CARES® Variobase™ Abutments
Straumann® CARES® Variobase™ Temporary abutments
Straumann® CARES® Variobase™ Copings
Straumann® Variobase™ Abutments

Common Name: Bonding Base
Patient-specific abutment coping

Classification Name: Endosseous dental implant abutment
Regulation Number: 21CFR872.3630

5.4 Predicate Devices

ETKON ES1, MODEL 019.0001, ETKON VISUAL, STRAUMANN CADCAM ABUTMENT	K093113
STRAUMANN CARES BRIDGE; STRAUMANN CARES DOLDER BAR	K101465
STRAUMANN DENTAL IMPLANT SYSTEM	K083550
NNC CEMENTABLE ABUTMENT STRAIGHT,15 DEGREE ANGLE, TYPE A ,15 DEGREE ANGLE, TYPE B,NNC BASAL SCREW CEMENTABLE ABUTMENTS	K113283
STRAUMANN COMPUTER AIDED RESTORATION SERVICE	K052272
STRAUMANN WN CARES TITANIUM ABUTMENT	K082764
P.004 NC CARES TITANIUM AND CERAMIC ABUTMENTS	K081005

P.004 RC CARES TITANIUM AND CERAMIC ABUTMENTS	K072151
LAVA FRAME, LAVA FRAME SHADE	K072055
SIRONA CAD/CAM SYSTEM	K100152
METOXIT CAM-BLANKS	K072569
NACERA Z AND NACERA Z MEDIUM	K080195
WIELAND ZENO CAO TEMPORARY PMMA DISC, TOOTH-COLORED	K071548

5.5 Description of the Device

5.5.1 Straumann® CARES® Variobase™ portfolio

The Straumann® CARES® Variobase™ portfolio consists of different parts which are used to provide prosthetic rehabilitation of a dental implant.
Premanufactured Variobase™ Abutments are available for the different platforms of the Straumann® dental implant system. These serve as a bonding base to which a patient-specific coping can be cemented. The coping can be made from ceramics to result in a permanent restoration, or made from acrylics to result in a temporary restoration (up to 180 days).
The coping can be fully anatomical, i.e. it is a replica of a tooth with incisal edge or occlusal surface. It may also be of a reduced tooth shape in which case a separate crown needs to be cemented onto the coping or direct veneering needs to be applied.

5.5.2 Straumann® Variobase™ Abutments

The premanufactured (stock) abutments of the Straumann® CARES® Variobase™ portfolio are sometimes also referred to as "bonding bases". Straumann® Variobase™ Abutments are available to fit to Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®) and RC (Regular CrossFit®).

5.5.3 Straumann® CARES® Variobase™ Copings

Straumann® CARES® Variobase™ Copings for Straumann® Variobase™ Abutments are patient-specific, CADCAM manufactured copings to be cemented to the Straumann® Variobase™ Abutments.
The copings are available in ceramic (zerion™) or in acrylic (polycon® ae) material. While the ceramic copings are intended to stay in the patient's mouth as a permanent restoration, the acrylic copings are intended for temporary restoration, i.e. use should be limited to 180 days.
Both materials, ceramic or acrylic, are available in different tooth colored shades.
By CAD (Computer Aided Design) and CAM (Computer Aided Manufacturing), the copings are produced so that they exactly connect to the corresponding bonding bases. The connection between the coping and the abutment is achieved by cementation.
Straumann® CARES® Variobase™ Copings are CADCAM manufactured from 510(k) cleared milling blanks.

Ceramic (zerion™): K072569, K080195
Acrylic (polycon® ae): K071548

The Straumann® CARES® Variobase™ Copings for CAMLOG® and NobelReplace™ abutments are patient-specific and can be used to restore abutments manufactured by CAMLOG® and Nobel Biocare®. It is available in ceramic and acrylic material.
A customer would need to carry out a 3D scan of a CAMLOG® or NobelReplace™ abutment. Based on the scan data the customer designs a coping that fits to the CAMLOG® or NobelReplace™ abutment. After CAM manufacturing the customer will receive the coping which he needs to cement to the abutment.
In such a case, Straumann only delivers the coping. The customer needs to get the abutment and screw from the original manufacturer (CAMLOG® or Nobel Biocare®).

510(k)s K072055 and K100152 describe similar design solutions, i.e. a patient-specific coping is designed to fit to a bonding base by a CAD system.

5.5.4 Straumann® CARES® Variobase™ Abutments

Straumann® CARES® Variobase™ Abutments zerion™ are a combination of the above mentioned components. Thus, a Straumann® CARES® Variobase™ Abutment consists of a Straumann® Variobase™ Abutment, the corresponding basal screw and a patient-specific Straumann® CARES® Variobase™ Coping zerion™.
Straumann® CARES® Variobase™ Temporary Abutments polycon® ae is comparable to the Straumann® CARES® Variobase™ Abutments zerion™, however, the coping in this case is made from acrylic.
The Straumann® CARES® Variobase™ Temporary Abutments polycon® ae is intended for temporary use (up to 180 days).
Straumann® CARES® Variobase™ Abutments are to be screw-fixed into a dental implant in the patient's mouth. The torque pressures of the screw are fully contained within the titanium interface.

5.6 Intended Use of the Device

Straumann® Variobase™ Abutments and Straumann® CARES® Variobase™ Abutments are prosthetic components that are directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitations.

The Straumann® CARES® Variobase™ Coping is patient-specific and can be used to restore abutments by Straumann®, CAMLOG® and NobelReplace™ abutments by Nobel Biocare®. It is available in zerion™ and polycon® ae.
The coping can be fully anatomical, i.e. it is a replica of a tooth with incisal edge or occlusal surface. It may also be of a reduced tooth shape in which case a separate crown needs to be cemented onto the coping or direct veneering needs to be applied.

5.7 Technological Characteristics

Straumann® Variobase™ Abutments are bonding bases made from a titanium-aluminum-niobium alloy. They are standard medical devices (stock produced).

Straumann® CARES® Variobase™ Copings is patient-specific medical devices, i.e. they are designed for an individual patient.
Straumann® CARES® Variobase™ Copings are designed either by a wax-up or a "CAD-up" procedure. Either way is processed through Straumann's CAD system consisting of the table top 3D-scanner Straumann® CARES® Scan CS2 and the corresponding CAD software Straumann® CARES® Visual. (CAD: Computer Aided Design)

In a wax-up procedure a wax model of a coping is created and scanned to be able to CAM produce the coping from a selected material. (CAM: Computer Aided Manufacturing)

In a "CAD-up" procedure, scanned data is used as the source to digitally design a coping. The design data is then sent to a Straumann milling center. The Straumann® CARES® Variobase™ Copings are CAM produced at the Straumann milling center according to the design file received and from the selected material.

Validation of the Straumann® CARES® Visual CAD software provides evidence that design parameters for the Straumann® CARES® Variobase™ Copings have met their pre-determined acceptance criteria and that dental restorations meeting their design specifications can be manufactured by Straumann CAM milling devices.

The software Straumann® CARES® Visual has been subject of 510(k) review and clearance in 510(k)s K093113 and K101465.

5.8 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11.

Bench testing was performed to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments and related product portfolio.

Dynamic fatigue tests were carried out in accordance to FDA's Guidance Document: *Root-form Endosseous Dental Implants and Endosseous Dental Abutments.*

Straumann® Variobase™ Abutments cemented to different Straumann® CARES® Variobase™ Copings passed the pre-defined acceptance criteria.

5.9 Substantial Equivalence Comparison

The following table lists the proposed devices Straumann® CARES® Variobase™ Abutments and the respective predicate devices Straumann is claiming substantial equivalence to.

Proposed Devices Straumann® CARES® Variobase™ Abutments				
NNC Narrow Neck CrossFit®	RN Regular Neck	WN Wide Neck	NC Narrow CrossFit®	RC Regular CrossFit®
Patient specific coping Straumann® CARES® Variobase™ Coping ZrO_2 for permanent use				
				
Patient specific coping Straumann® CARES® Variobase™ Coping PMMA for temporary use (up to 180 days)				
				
				
				
Predicate Devices				
Straumann® NNC Cementable Abutment Straight K113283	Straumann® CADCAM Abutment RN, Titanium K052272 K083550	Straumann® WN CARES® Titanium Abutment K082764	Straumann® NC CARES® Titanium Abutments K081005	Straumann® RC CARES® Titanium Abutments K072151

The proposed and the predicate devices share the following similarities.

	Proposed device Straumann® CARES® Variobase™ Abutments	**Predicate device**
Anatomical site	Oral cavity	Oral cavity
Implant-abutment-interface	Straumann Narrow Neck CrossFit® (NNC) Straumann Regular Neck (RN)	Straumann Narrow Neck CrossFit® (NNC) Straumann Regular Neck (RN)

	Straumann Wide Neck (WN) Straumann Narrow CrossFit® (NC) Straumann Regular CrossFit® (RC)	Straumann Wide Neck (WN) Straumann Narrow CrossFit® (NC) Straumann Regular CrossFit® (RC)
Implant-borne	Yes	Yes
Material of abutment	Titanium-aluminum-niobium	Titanium
Material of screws	Titanium-aluminum-niobium	Titanium-aluminum-niobium
Material of permanent coping	ZrO_2 (YTZ-P)	ZrO_2 (YTZ-P) **K072569, K080195**
Material of temporary coping	PMMA (polymethyl methacrylate)	PMMA (polymethyl methacrylate) **K071548**
Patient-specific design	CAD design by software Straumann® CARES® Visual	CAD design by software Straumann® CARES® Visual **K052272, K083550, K082764, K081005, K072151**
Duration of use	Permanent (coping made from ZrO_2) up to 180 days (coping made from PMMA)	Permanent
Sterility	Non sterile, to be sterilized by user	Non sterile, to be sterilized by user
Sterilization	Hot steam	Hot steam
Perform-ance testing	Dynamic fatigue tests of minimal body designs (Connection testing) The test specimens passed the pre-defined acceptance criteria.	**K113283**: Dynamic fatigue test of abutment (Connection testing) **K052272, K083550, K082764, K081005, K072151**: Dynamic fatigue tests of minimal body designs (Connection testing)
Indications for Use	Abutments are used in connection with the prosthetic restoration of Straumann® dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	**K113283**: Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges. Narrow Neck CrossFit Cementable Abutments are indicated for cement-retained single tooth and bridge restorations. **K052272, K083550**: Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann® CARES® Titanium Abutment is indicated for cemented restorations. The abutment can be used in single tooth replacements and multiple tooth restorations. **K082764**: Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures.

		The Straumann® WN CARES® Titanium Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained. **K081005**: Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures. The P.004 NC CARES® Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations. **K072151**: Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns or bridges. The P.004 RC CARES® Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations.

5.10 Conclusion

Non-clinical testing presented in this 510(k) premarket notification demonstrate that the components of the Straumann® CARES® Variobase™ portfolio met predefined acceptance criteria and successfully passed testing. The information presented in this 510(k) demonstrated that the components of the Straumann® CARES® Variobase™ portfolio are substantially equivalent to the predicate devices.

Straumann believes that the components of the Straumann® CARES® Variobase™ portfolio are safe and effective for their intended use.

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

December 21, 2012

Ms. Andreas Petermann
Director, Corporate Regulatory Affairs
Institut Straumann AG
Peter Merian-Weg 12
Basel
Switzerland CH-4052

Re: K120822
Trade/Device Name: Straumann® CARES® Variobase™ Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 14, 2012
Received: December 17, 2012

Dear Ms. Petermann:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
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): K120822

Device Name: Straumann® CARES® Variobase™ Abutments

Indications for Use:

The Straumann® CARES® Variobase™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crowns and bridges. Straumann® CARES® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

The Straumann® CARES® Variobase™ Coping polycon® ae in combination with the Straumann® Variobase™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental 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 CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.19 08:24:16 -05'00'

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

510(k) Number: K120822