Institut Straumann AG
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

February 22, 2018

Re: K171649
Trade/Device Name: Straumann CARES M-Series CAD/CAM System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: January 22, 2018
Received: January 23, 2018

Dear Jennifer Jackson:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See *PRA Statement below.*

510(k) Number *(if known)*

K171649

Device Name

Straumann CARES M-Series CAD/CAM System

Indications for Use *(Describe)*

The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14) Equivalent

510(k) Summary

Submitter: Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Contact Person: Jennifer M. Jackson, MS
Director of Regulatory Affairs and Quality

Prepared By: Gordon Dodds
Manager Design Control QM
Etkon GmbH

Date Prepared: February 21, 2018

Product Code(s): NHA (21 CFR 872.3630)
PNP (21 CFR 872.3630)

Device Class: II (21 CFR 872.3630)

Classification Panel: Dental

Classification Name: Endosseous dental abutment (21 CFR 872.3630)

Proprietary Name: Straumann® CARES M-Series CAD/CAM System

Predicate Device(s):
- K111421 SIRONA DENTAL CAD/CAM SYSTEM

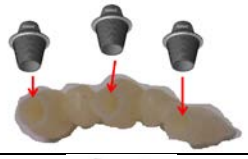
Reference Device(s):
- K120822 Straumann CARES Variobase Abutment
- K133421 Magellan Screw-Retained Abutments
- K152383 Ceramill ZOLID fx
- K063511 Ceramill ZI
- K151157 Variobase for Bridge/Bars
- K150899 Straumann CARES TAN Abutments
- K142890 Straumann Variobase Abutment
- K170354 Straumann Variobase Abutments
- K150203 Medentika CAD/CAM Abutments

Device Description: The Straumann CARES M-Series CAD/CAM System is intended for the design and fabrication of dental restorations by dental laboratories by means of a digital workflow.

The Straumann CARES M-Series CAD/CAM System employs optical impression files that document the topographical

characteristics of teeth, traditional dental impressions, or stone models. The Straumann CARES Visual CAD software then allows the design of the desired restorations. The CAM software converts the digital restoration design into the tooling and tool path commands needed to fabricate the restoration. The CAM software also allows multiple restoration files to be combined (nested) in order to maximize the use of dental material blanks. The milling command file is encrypted prior to transfer to the M-Series mill; this encryption ensures that files generated using other CAD or CAM software cannot be used with the M-Series mill. The user will load the milling command file into the M-Series mill where it is decoded. The user loads the appropriate dental material blank and initiates the milling operation.

The supported dental restorative devices are described in the following table:

Type	**Implant-borne**	**Picture**
Coping[1]	Using previously cleared Variobase Abutments	
Crown[1]	Using previously cleared Variobase Abutments	
Bridge[1]	Using previously cleared Variobase Abutments	
Abutment	Using subject Pre-Milled Abutment Blank	

[1] The combination of the coping, crown, or bridge and the Variobase Abutment component make up a two-piece abutment assembly, which is used in conjunction with endosseous dental implants for single or multiple tooth dental prostheses.

The digital workflow using the Straumann CARES M-Series CAD/CAM System includes the use of the following products:

D**ental Scanner(s)**

The Straumann CARES M-Series CAD/CAM can accept files generated using the following devices (note that these are not subject devices to this submission):

- Dental Wings Intra-Oral Scanner, DWIO
- Dental Wings 3-Series & 7-Series desktop scanners (extra-oral)
- Straumann CARES CS2 scanner (extra-oral)

The dental scanner takes optical impressions that document the topographical characteristics of teeth, traditional dental impressions, or stone models. This includes the location and orientation of dental implants or abutments when a Scanbody is employed during the scan.

CARES Visual CAD Software

The CARES Visual software is a dental CAD application that allows the user to digitally design dental restorations, based on information that was acquired by a dental scanner. As a result of the design process and the indication and material dependent dimensional limits, a three-dimensional geometry is created that is linked to the selected restorative material/milling blank. The use of Straumann manufacturer provided digital device models assures the accuracy of the interfaces between the designed restoration and the abutment or implant being restored.

CARES Visual CAM Module

The CAM interface module converts the three-dimensional geometry into milling machine control data. The CAM software uses the digital restoration geometry information and the material selection to define the tools to be used, the paths the tools are to follow to re-create the digital geometry in physical form and the speed and feed rates of the mill and the tooling. The CAM software also allows for multiple restoration files to be fit within the geometry of a single dental material blank (a process referred to as nesting) in order to maximize the use of dental material blanks.

The completed CAM file is encrypted prior to being output for transfer to the milling machine. This encryption ensures that files generated using other CAD or CAM software cannot be used with the M-Series mill. This is a means of assuring that only the validated product configuration is used.

Straumann M-Series Milling Machine

The milling machine receives the CAM file from the CAM software. The user will load the CAM file into the M-Series mill where it is decoded. The user loads the appropriate dental material blank, tools and burs. For certain materials the user will also employ a cutting fluid that acts as a lubricant and coolant for the milling operation. Once the machine is fully configured, the user initiates the milling operation.

Sintering Furnace

- Straumann Therm

Some restoration materials are provided in a green (i.e. partially crystallized) state or are combined with a polymeric binder material. This is typically done to make the machining process easier and to increase tool life. These materials must undergo a sintering process after milling in order to achieve their final form. This is carried out in a sintering furnace.

The materials that require sintering are to be larger than the final finished restoration to account for the shrinkage that will occur during sintering. This scaling is included in the CAD software as a material specific parameter. The CAD software will scale the digital restoration design using this parameter prior to transfer of the data to the CAM software in order to assure that the final, sintered restoration accurately reflects the digital design.

Restoration Material Milling Blanks

A selection of milling blanks is available for use with the Straumann CARES M-Series CAD/CAM system. Straumann will market its own material Straumann® n!ce, Ivoclar's IPS e.max CAD and co-branded versions of milling blanks currently marketed by Amann Girrbach in the United States. These materials and their design control limits are identified in the table below.

Product Name	***Material***	***Min post height mm***	***Max angulation***	***Min Gingiva height mm***	***Min wall thickness mm***
Zi	ZrO_2	4.0	30°	1	0.6
Zolid HT	ZrO_2	4.0	30°	1	0.6
Zolid SHT	ZrO_2	4.0	30°	1	0.95
Zolid HT Preshade	ZrO_2	4.0	30°	1	0.6
n!ce	Glass ceramic	4.0	30°	1	1.05
IPS e.max CAD	Glass ceramic	4.0	30°	1	0.75 to pre-molar 0.95 molar

This submission also introduces new milling blanks suitable for fabricating solid customized abutments that attach directly to the implants of the Straumann Dental Implant System. The Pre-Milled Abutment Blank devices are produced from Ti-6Al-7Nb alloy. They have the designated Straumann implant-to-abutment connection pre-milled at the apical end of the blank. The emergence profile and coronal segments of the blank consists of a solid cylinder available in one 12 mm diameter. The four configurations and design control limits are shown in the table below.

Product Name	***Material***	***Implant-to-Abutment Interface***	***Min post surface area***	***Max angultation***	***Min wall thickness mm***	***Min Gingiva height mm***
PMAB	TAN	Bone Level Narrow CrossFit® (NC)	37 mm² to 56 mm² dependent on tooth position This corresponds to a minimum height of ~4 mm	30°	0.4	0.87
PMAB	TAN	Bone Level Regular CrossFit® (RC)		30°	0.4	0.87
PMAB	TAN	Tissue Level Regular Neck (RN)		30°	0.4	N(A
PMAB	TAN	Tissue Level Wide Neck (WN)		30°	0.4	N/A

The following schematic illustrates how the different components of the CARES M-Series CAD/CAM system work together.

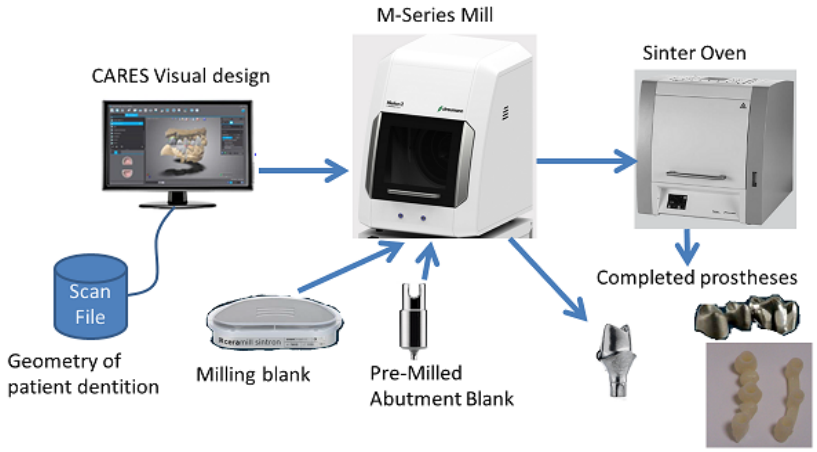


Figure 1 Workflow from scanning to completed prostheses

Indications For Use:

The Straumann® CARES® M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.

Intended Use:

The Straumann CARES M-Series CAD/CAM System is intended to be used for the design and fabrication of patient-specific dental restorations. The dental restorations are intended to restore dental implants, either directly (CAD/CAM milled abutment) or via a Ti-base style abutment (Straumann trade name Variobase).

The Straumann CARES M-Series CAD/CAM System also supports the design and fabrication of two styles of implant-borne dental restorations. Prostheses consist of stock Variobase Abutments (generically known as Ti-bases) with customized ceramic or glass-ceramic restorations cemented in place that mount directly onto Straumann NC, RC, RN and WN implants. The combination of the ceramic restoration and Variobase Abutment component make up a two-piece abutment assembly which is used in conjunction with endosseous dental implants for single or multiple tooth dental prostheses, see Figure 2 for examples of the Variobase/restoration two-piece combinations.

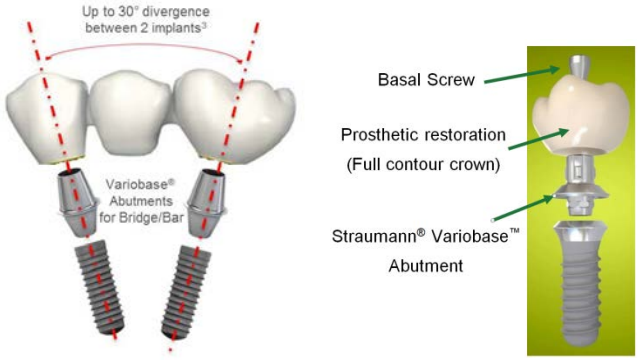


Figure 2 Two-piece Straumann® Variobase™ Abutments for Bridges/Bars (left) and Crowns (right)

The Straumann CARES Pre-Milled Abutment Blank (PMAB) is designed and milled to create a customized abutment that engages directly to the implant. The implant engaging part and screw-seat/channel of the CARES Pre-Milled Abutment Blank is already pre-manufactured by Straumann as delivered to the customer and will not be modified by milling in the laboratory, see Figure 3.

Figure 3 Left: PMAB with milling machine clamping mechanism at top and pre-milled interface to dental implant at bottom.
Right: Patient-specific abutment milled from a blank

Materials:

Milling Blank	***Material***
Pre-Milled Abutment Blank	TAN (Ti6A7Nb)
Ceramill ZOLID fx (Straumann brand Zolid SHT)	ZrO_2 (YSZ)- Yttria-stabilized zirconia
Ceramill Zi (Straumann brand Zolid HT and Zi)	ZrO_2 (YSZ)
IPS e.max CAD	Lithium-disilicate glass-ceramic
n!ce	Lithium-aluminosilicate with Lithium-disilicate glass-ceramic

Pre-Milled Abutment Blanks are manufactured from titanium-6aluminum-7niobium alloy (TAN). This material is identical to the material used to produce the reference CARES TAN Abutments (K150899).

Technological Characteristics:

See Table below

Table 1: Substantial Equivalence Comparison – Straumann CARES M-Series CAD/CAM System

FEATURE	SUBJECT Straumann® CARES® M-Series CAD/CAM System	PREDICATE SIRONA DENTAL CAD/CAM SYSTEM (K111421)	Equivalence Discussion
Indications for Use	The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5 Land SBL 3.3 L, the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: • Nobel Biocare Replace (K020646) • Nobel Biocare Branemark (K022562) • Friadent Xive (K013867) • Biomet 3i Osseotite (K980549) • Astra Tech Osseospeed (K091239) • Zimmer Tapered Screw-Vent (K061410) • Straumann SynOcta (K061176)	**Equivalent** The basic indication of providing support for prostheses scanning, design and fabrication is the same. Support for TiBase-borne restorations is the same. The subject device indications refer to fabrication of coping, crowns and bridges. The proposed copings, crowns and bridges include the mesostructure (or top-half of two-piece abutment), which are the same as referenced in the primary predicate indications. The crowns and bridges of the subject device may be referred to as hybrid abutments and are therefore equivalent. The subject device also supports the fabrication of implant connected solid abutments.

FEATURE	SUBJECT Straumann® CARES® M-Series CAD/CAM System	PREDICATE SIRONA DENTAL CAD/CAM SYSTEM (K111421)	Equivalence Discussion
		• Straumann Bone Level (K053088, K062129, K060958) • Biomet 3i Certain (K014235, K061629) • Nobel Biocare Active (K071370)	
Source of Input Files	Intra-Oral Scanner Bench-top Scanners	Bench-top scanners	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device.
Bench Scanner Control	Yes	Yes	**Equivalent**
Implant Detection	Yes, using Scanbodies	Yes, using Scanbodies	**Equivalent**
Design Environment	Straumann CARES Visual: Closed CAD System facilitating the design of restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	Sirona Dental CAC/CAM Software Closed CAD System facilitating the design of restorations used in conjunction with the Sirona TiBase devices and Camlog Titanium Base CAD/CAM devices.	**Equivalent** Both systems support the design and fabrication of device-borne restorations, but for devices from different companies.
Restoration Types Supported	Device-borne: Copings and crowns for Variobase Abutments Copings, crowns and bridges for Screw-Retained Abutments Bridges and bars for Variobase for Bridge/Bar Abutments Solid TAN Abutments for Straumann Implants	Device-borne: Copings and crowns for TiBase devices Copings and crowns for Camlog Titanium Base devices	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device. Both devices allow design and fabrication of the mesostructure for a two-piece abutment (standard coping or hybrid crown/bridge). The subject device also allows design and fabrication of a one-piece titanium abutment. The areas of the abutment available for design are equivalent.
Supported Hardware Devices	• Straumann Variobase Abutments for NC, RC, NNC, RN and WN implant-to-abutment interfaces (K120822). • Straumann Variobase Abutments for Bridges and Bars for NC, RC, NNC, RN	• Sirona Ti-bases for use with the following implant systems: • Nobel Biocare Replace (K020646) • Nobel Biocare Branemark (K022562) • Friadent Xive (K013867) • Biomet 3i Osseotite (K980549) • Astra Tech Osseospeed (K091239)	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device related to support for titanium base style abutments. The subject devices

FEATURE	SUBJECT Straumann® CARES® M-Series CAD/CAM System	PREDICATE SIRONA DENTAL CAD/CAM SYSTEM (K111421)	Equivalence Discussion
	and WN implant-to-abutment interfaces (K151157) • Copings for Straumann Screw-Retained Abutments (K133421). • Solid abutments for connection with NC, RC, RN and WN implants of the SDIS using the subject Pre-Milled Abutment Blanks.	• Zimmer Tapered Screw-Vent (K061410) • Straumann SynOcta (K061176) • Straumann Bone Level (K053088, K062129, K060958) • Biomet 3i Certain (K014235, K061629) • Nobel Biocare Active (K071370) • Camlog Titanium Base CAD/CAM	provide support for implant connected abutments.
Supported Restorative Materials	• Ceramill ZOLID fx ZrO_2 • Ceramill ZI ZrO_2 • Ceramill ZOLID ZrO_2 • Titanium-6Aluminum-7Niobium alloy or TAN (Subject Pre-Milled Abutment Blanks) • Ivoclar IPS e.max CAD • Straumann n!ce Glass Ceramic	• InCoris pre-sintered Ceramic (K062509) ZrO_2	**Equivalent** ZrO_2 Ceramic material with indications according to ISO 6872 Classification are equivalent. The ZrO_2 materials for use with the Straumann CARES M-Series CAD/CAM System have been previously cleared by FDA. The TAN material is identical to material used in CARES TAN Abutments cleared to market per K150899. Straumann n!ce Blocks for Amann Girrbach were previously cleared per K170420. The use of the Iovclar IPS e.max CAD material with Variobase Abutments has been cleared per K142890. The use of the n!ce material with Variobase Abutments has been cleared per K170354.
Restoration Sizes	Device-borne: Single crown up to 16-Unit bridge	Device-borne: Single crown	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device. Support of bridges through two or more implants is achieved through Variobase for

FEATURE	SUBJECT Straumann® CARES® M-Series CAD/CAM System	PREDICATE SIRONA DENTAL CAD/CAM SYSTEM (K111421)	Equivalence Discussion
			Bridge/Bar abutments (K151157). Use of multiple implants in the bridge limit the force on the individual implant to be less or equivalent to that of the single crown. For a 16-unit bridge, the force is spread over 4 or more implants.
Interface to Ti-Base	Milled by the system using solid restoration material discs or C14 blocks	Pre-milled in the A14 block material	**Equivalent** The ability of the subject device to use solid blocks provides greater design flexibility to the user.
CAD to CAM Transfer	Seamless, same software interface	Seamless, same software interface	**Equivalent**
CAM Capability	Nesting of multiple designs to maximise use of material discs Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration Encryption of milling file	Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device.
CAM to Mill Transfer	Encrypted file format assures that the M-Series, Mills can only accept files generated by the Straumann CARES Visual and CAM Module software	It would be expected that the transfer is encrypted – the transfer protection mechanism is not publically available.	**Equivalent** Capabilities of subject device include or exceed the scope of capabilities for the predicate device.
Supported Mills	Straumann CARES M-Series, Mills	CEREC MCXL Mill inLab MCXL Mill	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device.
Fabrication Workflow	Dry milling of partially crystallized ceramic blanks Wet milling of Ti-6Al-7Nb Pre-Milled Abutment Blanks, Ivoclar IPS e.max CAD and n!ce Glass Ceramic using coolant	In-lab wet milling of pre-sintered ceramic blocks using coolant	**Equivalent** Capabilities of subject device include the scope of capabilities for the predicate device.

FEATURE	SUBJECT Straumann® CARES® M-Series CAD/CAM System	PREDICATE SIRONA DENTAL CAD/CAM SYSTEM (K111421)	Equivalence Discussion

Table 2: Substantial Equivalence Comparison – Abutment Borne Restorations

Feature	SUBJECT Straumann Variobase Abutments	PREDICATE Straumann Variobase Abutments (K142890, K120822)	Equivalence Discussion
Indications for Use	The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	**Identical**
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	**Identical**
Abutment Diameter	3.8 – 7.0 mm	3.8 – 7.0 mm	**Identical**
Abutment Height	3.5 – 4.5 mm	3.5 – 4.5 mm	**Identical**

Feature	SUBJECT Straumann Variobase Abutments	PREDICATE Straumann Variobase Abutments (K142890, K120822)	Equivalence Discussion
Coping/ Crown Material	The following materials are being added to the previously cleared coping/crown materials: Amann Girrbach Ceramill ZOLID ZI (ZrO_2) Amann Girrbach Ceramill ZOLID HT (ZrO_2) Amann Girrbach Ceramill ZOLID SHT (ZrO_2) Amann Girrbach Ceramill ZOLID HT Preshade (ZrO_2) Ivoclar IPS e.max CAD (K142890) Straumann n!ce Glass Ceramic (K170354)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	**Equivalent** The digital workflow is being expanded to add additional materials. . The Zi, ZOLID series of materials are equivalent to the zerion ZrO_2 material. **Identical** The use of the n!ce material with Variobase Abutments is identical to K170354. The use of the Ivoclar IPS e.max CAD with Variobase Abutments is identical to K142890.
Design Workflow	CAD	Wax-up or CAD	**Equivalent** The subject device employs a subset of the techniques employed for the predicate devices.
Fabirication Workflow	Milling by the dental laboratory	Traditional casting or pressing by the dental laboratory or CAM by Straumann Milling Center	**Equivalent** The restorations milled by the dental laboratory are equivalent to those produced by the Straumann milling center.
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	**Identical**
Reusable	No	No	**Identical**

Table 3: Substantial Equivalence Comparison – Implant-Borne Restorations

Feature	Subject Laboratory Milled CARES® TAN Abutments	Predicate Straumann® CARES® TAN Abutments (K150899)	Equivalence Discussion
Indications for Use	The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as **milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.**	The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.	**Identical**
Abutment Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb, TAN)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb, TAN)	**Identical**
Abutment Apical Design	Engaging **BoneLevel** Narrow CrossFit (NC) Regular CrossFit (RC) **Tissue Level** Regular Neck (RN) Wide Neck (WN)	Engaging **BoneLevel** Narrow CrossFit (NC) Regular CrossFit (RC) **Tissue Level** Regular Neck (RN) Wide Neck (WN)	**Identical**

Feature	Subject Laboratory Milled CARES® TAN Abutments	Predicate Straumann® CARES® TAN Abutments (K150899)	Equivalence Discussion
Abutment Coronal Design	CADCAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.	CADCAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.	**Identical**
CAD Design Limits	Max. Angulation 30° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.4 mm Smooth Distance 0.5 mm Min post surface area 37 to 56mm²	Max. Angulation 30° Emergence Offset 0.1 mm Emergence Angle 65° Min. Thickness 0.4 mm Smooth Distance 0.5 mm Min post surface area 37 to 56mm²	**Identical**
Fabrication Method	Dental laboratory mills using the Straumann CARES M-Series CAD/CAM Systems and the subject Pre-Milled Abutment Blank.	CAM by Straumann Milling Center.	**Equivalent** Both methods make use of the Straumann CARES Visual CAD software to design the abutment, so the same validated limits are applied. The difference is the transition from a QSR controlled manufacturing location to a dental laboratory. The milling accuracy of the Straumann CARES M-Series CAD/CAM System has been validated. Labeling has been revised and validated for milling unit installation, maintenance, and required tools/machine liquids/material blocks to ensure equivalence.
Directly Veneerable?	Yes	Yes	**Identical**

Performance Data:

Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. The following testing has been conducted and is summarized for each new material and device type in the table below, with reference to predicates:

- Dynamic fatigue testing conforming to FDA guidance and ISO 14801.
- Software validation conforming to the requirements of IEC 62304.
- Sterilization validation conforming to ISO 17665-1 and ISO/TS 17665-2.
- Biocompatibility testing conforming to ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-18.
- Electrical safety testing conforming to IEC 61010-1 and IEC 61010-2-010.

Variobase materials	Fatigue tests - predicates	Sterilization validation predicates	Biocompatibility testing – predicates
Zi	K142890	K142890	K063511
Zolid HT	K142890	K142890	K063511
Zolid SHT	K142890 K150203	K142890	K152383
n!ce	K170354	K170354	K170354
IPS e.max CAD	K142890	K142890	K142890

PMAB materials	Fatigue tests predicates	Sterilization validation predicates	Biocompatibility testing – predicates
TAN	K150899	K150899	K150899

Conclusions:

Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.