June 23, 2021

Institut Straumann AG
℅ Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K203456
    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: June 7, 2021
    Received: June 8, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
    Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K203456

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

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On behalf of: Institut Straumann AG Peter Merian Weg, 12 CH-4002 Basel, Switzerland
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Date of Submission:	June 22, 2021

Name of the Device

Trade Names:	Straumann® CARES M-Series CAD/CAM System
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	II
Product Code(s):	NHA, PNP
Classification Panel:	Dental

K203456 – Special 510(k)

Straumann® CARES M-Series CAD/CAM System

510(k) Summary

Predicate Device(s)

Primary Predicate:

- K171649 – Straumann® CARES M-Series CADCAM System

Reference Devices:

- K190040 – Straumann BLX Line Extension - New Abutments
- K190082 – Straumann® BLX Variobase® Abutment
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems

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 workflow is unchanged from the primary predicate K171649. This premarket notification is introducing the Straumann Variobase Abutments for the BLX implant to abutment interface to the previously cleared 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.

This premarket notification includes restorations (copings, crowns, and bridges) manufactured from Zolid HT/Zolid SHT materials for cementation on Straumann Variobase Abutments for the BLX implant system. The BLX dental implant platforms include RB (Regular Base) and RB/WB (Regular Base/Wide Base). 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.

Straumann® CARES M-Series CAD/CAM System

510(k) Summary

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

Dental Scanner(s)

The Straumann CARES M-Series CAD/CAM system 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 the 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 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® CARES M-Series CAD/CAM System

510(k) Summary

<u>Straumann M-Series Milling Machine</u>

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 mounts 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.

<u>Sintering Furnace</u>

- 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 milled geometries, in the materials that require sintering, are 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.

<u>Restoration Material Milling Blanks</u>

A selection of milling blanks is available for use with the Straumann CARES M-Series CAD/CAM system. The materials and their design control limits are identified in Table 1.

Material Name	Material	Minimum Post Height (mm)	Maximum Angulation	Minimum Wall Thickness (mm)
Zolid HT	ZrO_2	4.0	30˚	0.6
Zolid SHT	ZrO_2	4.0	30˚	0.95
Zolid HT Preshade	ZrO_2	4.0	30˚	0.6

Table 1 – Materials with design control limits for use with Straumann BLX Variobase Abutments

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.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate device, Straumann CARES M-Series CAD/CAM System, and the reference devices in Table 2. The main technological difference is the implant to abutment interface of the Variobase Abutments. The BLX Variobase Abutments were cleared previously for centralized manufacturing at a Straumann Validated Milling Center with different restoration materials in K190040 and K190082. The in-lab workflow and the restoration materials (Zolid HT and Zolid SHT) are identical to the primary predicate.

K190662 is not included in Table 2 and is referenced for the MRI compatibility only.

FEATURE	SUBJECT DEVICE K203456	PRIMARY PREDICATE DEVICE K171649	REFERNCE DEVICE K190082	REFERENCE DEVICE K190040	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 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.	Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	**Straumann BLX Healing Abutments for Bars and Bridges** Straumann Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. Healing components have a maximum duration of usage of 6 months. **Straumann BLX Temporary Abutments for Bars and Bridges** Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated. BLX Temporary Abutments have a maximum duration of usage of 180 days. **Straumann BLX Variobase Abutments for Bar and Bridges** Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or overdenture) can be cemented on the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into	Identical to primary predicate

FEATURE	SUBJECT DEVICE K203456	PRIMARY PREDICATE DEVICE K171649	REFERNCE DEVICE K190082	REFERENCE DEVICE K190040	EQUIVALENCE DISCUSSION
				occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. **Straumann BLX Variobase Abutments AS** The Straumann Variobase for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center. **Straumann BLX Novaloc Abutments** The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants. **Straumann BLX CARES Abutments** The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.	
Source of Input Files	Intra-Oral Scanner Bench-top Scanners	Intra-Oral Scanner Bench-top Scanners	N/A	N/A	Identical to primary predicate
Bench Scanner Control	Yes	Yes	N/A	N/A	Identical to primary predicate
Implant Detection	Yes, using Scanbodies	Yes, using Scanbodies	N/A	N/A	Identical to primary predicate

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Straumann® CARES M-Series CAD/CAM System

510(k) Summary

FEATURE	SUBJECT DEVICE K203456	PRIMARY PREDICATE DEVICE K171649	REFERNCE DEVICE K190082	REFERENCE DEVICE K190040	EQUIVALENCE DISCUSSION
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).	Straumann CARES Visual: Closed CAD System facilitating the design of restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	N/A	N/A	Identical to primary predicate
Restoration Types Supported	Device-borne: Copings and crowns for Variobase Abutments Bridges and bars for Variobase for Bridge/Bar Abutments	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 Variobase Abutments	Device-borne: Bridges and bars for Variobase for Bridge/Bar Abutments	Included in primary predicate Identical to reference devices
Compatible Implants	Straumann Bone Level implants having the WB, RB/WB implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC, RN, and WN implant-to-abutment interface geometries.	Straumann Bone Level implants having the WB, RB/WB implant-to-abutment interface geometries.	Straumann Bone Level implants having the WB, RB/WB implant-to-abutment interface geometries.	Identical to reference devices
Abutment Platform Diameters	3.8 – 5.5 mm	3.8 – 7.0 mm	3.8 – 5.5 mm	4.5 mm	Identical to reference devices
Abutment Gingiva Height (Bone Level only)	1.5 – 3.5 mm	1.0 – 3.0 mm	1.5 – 3.5 mm	1.5 mm	Identical to reference devices
Abutment Material	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Identical

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Straumann® CARES M-Series CAD/CAM System

510(k) Summary

FEATURE	SUBJECT DEVICE K203456	PRIMARY PREDICATE DEVICE K171649	REFERNCE DEVICE K190082	REFERENCE DEVICE K190040	EQUIVALENCE DISCUSSION
Supported Restorative Materials for Ti-Bases	Amann Girrbach Ceramill ZOLID HT (ZrO$_2$) Amann Girrbach Ceramill ZOLID SHT (ZrO$_2$) Amann Girrbach Ceramill ZOLID HT Preshade (ZrO$_2$)	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)	Two-piece abutment base with bonded prosthesis produced via: Digital Workflow: coron® zerion® LT zerion® ML and UTML	Two-piece abutment base for bridges/bars/overdentures with bonded prosthesis produced via: Materials cleared by the FDA under 21 CFR 872.6660 or exempt materials as described under 21 CFR 872.3060 (Noble metal alloys) and 21 CFR 872.3710 (Base metal alloys).	Identical to Primary Predicate
Maximum Angulation	30° controlled in design software	30° controlled in design software	30° controlled in design software	30° controlled in design software	Identical
Restoration Sizes	Device-borne: Single crown up to 16-Unit Bridge	Device-borne: Single crown up to 16-Unit Bridge	Device-borne: Single crown	Device-borne Bars/Bridges/Overdentures: Up to 16-Unit Bridge	Identical to Primary Predicate
Interface to Ti-Base	Milled by the system using solid restoration material discs	Milled by the system using solid restoration material discs or C14 blocks	N/A	N/A	Identical to Primary Predicate
CAD to CAM Transfer	Seamless, same software interface	Seamless, same software interface	N/A	N/A	Identical to Primary Predicate
CAM Capability	Nesting of multiple designs to maximize use of material disks. Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration. Encryption of milling file.	Nesting of multiple designs to maximize use of material disks. Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration. Encryption of milling file.	N/A	N/A	Identical to Primary Predicate
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	Encrypted file format assures that the M-Series Mills can only accept files generated by the Straumann CARES Visual and CAM Module Software	N/A	N/A	Identical to Primary Predicate
Supported Milles	Straumann CARES M-Series Mills	Straumann CARES M-Series Mills	N/A	N/A	Identical to Primary Predicate

K203456 – Special 510(k)

Straumann® CARES M-Series CAD/CAM System

510(k) Summary

FEATURE	SUBJECT DEVICE K203456	PRIMARY PREDICATE DEVICE K171649	REFERNCE DEVICE K190082	REFERENCE DEVICE K190040	EQUIVALENCE DISCUSSION
Fabrication Workflow	Dry milling of partially crystallized ceramic blanks.	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.	N/A	N/A	Identical to Primary Predicate
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Identical

Table 2 – Comparison of subject device versus primary predicate device

Performance Testing

Comparative dynamic fatigue tests were conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" and demonstrated the Straumann BLX Variobase® with Zolid SHT and Zolid HT crowns are equivalent to the primary predicate and reference devices.

The Milling System Validation was leveraged from K171649 to confirm the dimensions of the milled restoration were the same as the intended CAD design from CARES Visual. A Simulated Use validation was also leveraged from K171649 to confirm the scan, design, and production capability of the subject devices in CARES Visual. The subject devices were not considered a new worst case; therefore, the existing validations were referenced.

The subject device materials are identical to the predicate and reference device materials, therefore, no new issues regarding biocompatibility were raised.

The sterilization process for the Straumann Variobase® as recommended in the labeling was validated according to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015*".

Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann BLX Variobase® Abutments restored with Zolid HT and Zolid SHT restorations manufactured via the Straumann CARES M-Series CAD/CAM System workflow are substantially equivalent to the primary predicate and reference devices.