October 9, 2021

Institut Straumann AG
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K203750
Trade/Device Name: Straumann CARES P-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: September 15, 2021
Received: September 16, 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,

for Andrew 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203750

Device Name

Straumann CARES P-Series CAD/CAM System

Indications for Use *(Describe)*

The Straumann CARES P-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, a restorative acrylic resin, 3D printers, post-curing unit and associated accessories. The system is used to design and fabricate CAD/CAM 3D printed coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, that are affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.

The Straumann P pro Crown & Bridge material in combination with the Straumann Variobase is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.

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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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
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By:	Gordon Dodds Manager Design Control QM Etkon GmbH
Date of Submission:	September 30, 2021

Name of the Device

Trade Names:	Straumann CARES P-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

Predicate and Reference Device(s)

Primary Predicate:

- K171649 - CARES M-Series CADCAM System

Reference Devices:

- K200039 – P pro Crown & Bridge (DeltaMed GmbH)
- K120822 – Straumann CARES Variobase® Abutment NNC, RN, WN, NC, RC
- K173968 – CARES Variobase® for Bridge/Bar Cylindrical (Institut Straumann AG)
- K173379 – Variobase® AS (Institut Straumann AG)
- K190662 – MR I Compatibility for Existing Straumann Dental Implant Systems (Institut Straumann AG)
- K190082 – Straumann® BLX Variobase® Abutment (Institut Straumann AG)
- K190040 – Straumann BLX Line Extension - New Abutments (Institut Straumann AG)
- K100247 – DETAX Implantlink Semi Classic cement

Device Description

The Straumann CARES P-Series CAD/CAM System is intended for the design and fabrication of dental restorations by dental laboratories by means of a digital workflow for 3D printing.

The Straumann CARES P-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 sequential slice geometries needed to 3D print a restoration or multiple restorations in a print job. The printing file is transferred to the Straumann P-Series 3D printer; where it is decoded into the defined printing slices and the user initiates the printing operation. The Straumann P-Series 3D printer will then print the designed restoration using the Straumann P Pro Crown & Bridge resin.

The user of a Straumann CARES P-Series CAD/CAM System can design dental implant borne restorations using Straumann Variobases as the connecting interface to the implant. By this, the user will create two-piece abutments with the 3D printed part being the upper part of the implant borne restoration.

The Straumann Variobases that can be restored via the Straumann CARES P-Series CAD/CAM System include the following models and platforms:

- RC (Regular CrossFit®)
- NC (Narrow CrossFit®)
- RN (Regular Neck)
- WN (Wide Neck)
- RB (Regular Base)
- RB/WB (Regular Base/Wide Base)

The Straumann® Variobases are pre-manufactured (stock) items, sometimes referred to as "Ti-bases", made from a titanium-aluminum-niobium (Ti6Al7Nb, TAN) alloy. They are the bottom half of the two-piece abutment.

The 3D printed polymeric portion of the dental restoration will have a connecting interface to the coronal aspect of the Variobase, so that it can be cemented to that connecting interface. The 3D printed items feature a screw channel hole so that the cemented two-piece abutment can be affixed via a basal screw to the dental implant. The dental restoration is the top half of the two-piece abutment.

The different types of restorations are described in Table 1.

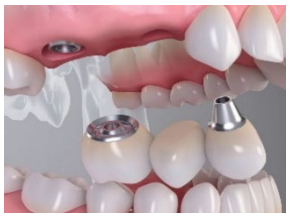
Type	Implant-borne	Image
Single unit	Using previously cleared Variobase Abutments	
Multi-unit	Using previously cleared Variobase Abutments	

Table 1 – Types of restorations

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

Dental Scanner(s)

The Straumann CARES P-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)

The dental scanner takes optical impressions that record 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 the Straumann P pro Crown & Bridge design dimension limits, a three-dimensional geometry is created. The use of Straumann provided digital device models (interface library) assures the accuracy of the interfaces between the designed restoration and the Variobase® being restored.

CAM Module

The CAM interface module converts the digital three-dimensional restoration geometry into the layer geometries for the 3D printer.

Straumann P-Series 3D printer

The 3D printer receives the CAM file from the CAM software. The user loads the CAM file into the Straumann P-Series 3D printer and initiates the 3D printing process.

Centrifuge

A centrifuging process is carried out to remove non polymerized resin from the surface of the printed dental restoration, without the use of a solvent, before the curing process.

Post Curing

After the centrifuge process, the printed restorations need to undergo a final light-induced polymerization process, so that the device achieves its tested physical and mechanical characteristics.

3D printing resin

The Straumann P pro Crown & Bridge resin is the raw material used to create the 3D printed restorations. The material is available in three different color shades, A1, A2 and A3. The Straumann P pro Crown & Bridge material has received 510(k) clearance through K200039, as a temporary restoration for crowns and bridges (CFR 872.3770, Product Code EBG). The Straumann P pro Crown & Bridge resin device in this submission, while of the same material composition, is for use as an endosseous dental implant abutment (CFR 872.3630, Product Code NHA). The P pro Crown & Bridge design specifications for crowns and bridges are:

Restoration type	Parameter	Value
Crown	Minimum wall thickness	1.0 mm
	Maximum angulation	30°
	Minimum post-height of Variobase combined with P pro Crown& Bridge crown	4.6 mm
	Minimum diameter	3.8 mm
Bridge	Minimum wall thickness	1.0 mm
	Maximum angulation	30°
	Minimum post-height of Variobase combined with P pro Crown& Bridge abutment	4.6 mm
	Minimum diameter	3.8 mm
	Maximum number of units	6
	Maximum number of pontics	2
	Minimum cross-section of connector anterior/posterior	12 mm²/ 14 mm²

Table 2 – Design parameters for 3D printed restorations from Straumann P pro Crown & Bridge

Intended Use

The Straumann CARES P-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 via a Ti-base style abutment (Straumann tradename Variobase).

Indications for Use

The Straumann CARES P-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, a restorative acrylic resin, 3D printers, post-curing unit and associated accessories. The system is used to design and fabricate CAD/CAM 3D printed coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments that are affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.

The Straumann P pro Crown & Bridge material in combination with the Straumann Variobase is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate device in Table 3.

K203750 – Traditional 510(k)

Straumann CARES P-Series CAD/CAM System

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	**Subject Device**	**K171649**
Indications for Use	Straumann CARES P-Series CAD/CAM System The Straumann CARES P-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, a restorative acrylic resin, 3D printers, post-curing unit and associated accessories. The system is used to design and fabricate CAD/CAM 3D printed coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments that are affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw. The Straumann P pro Crown & Bridge material in combination with the Straumann Variobase is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.	Straumann CARES M-Series CAD/CAM System 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.
Source of Input Files	Intra-Oral Scanner Bench-top Scanners	Intra-Oral Scanner Bench-top Scanners
Bench Scanner Control	Yes	Yes
Implant Detection	Yes, using Scanbodies	Yes, using Scanbodies
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).
Restoration Types Supported	Single unit restorations and bridges for Straumann Variobases	Single unit restorations and bridges for Straumann Variobases
Supported Variobases	Straumann Variobase Abutments for NC, RC, RN and WN implant-to-abutment interfaces (K120822). Straumann Variobase Abutments for Bridges and Bars for NC, RC, RN and WN implant-to-abutment interfaces (K173968) Copings for Straumann Screw-Retained Abutments (K133421). Straumann Variobase AS (K173379) Straumann Variobase BLX (K190082) Straumann BLX Varibase for Bar & Bridge (K190040)	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 and WN implant-to-abutment interfaces (K151157) Copings for Straumann Screw-Retained Abutments (K133421).
Supported Restorative Materials	Straumann P pro Crown & Bridge (K200039)	Zirconia and glass ceramic milling blanks
Restoration Sizes	Single crown up to 6-unit bridge	Single crown up to 16-unit bridge

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	**Subject Device**	**K171649**
Interface to Variobase	3D printed by the system	Milled by the system
CAD to Local Production Transfer	Straumann CARES Visual output STL is converted to printing layer format using Netfabb software and transferred to printer	Straumann CARES Visual output geometry is converted to a milling tool path sequence using Moduleworks software and transferred to mill
Supported manufacturing equipment	Straumann CARES P-Series 3D printers	Straumann CARES M-Series mills
Fabrication Workflow	3D printing (additive)	Milling (subtractive)
Compatible Implants	Straumann Bone Level implants having the NC, RC, RB and RB/WB implant-to-abutment interface geometries. Straumann Tissue Level implants having the RN, and WN 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.
Abutment Platform Diameters	3.8 mm – 7.0 mm	3.8 mm – 7.0 mm
Material of Variobase	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)
Material of restoration	Acrylic - P Pro Crown & Bridge	ZrO_2
Lifetime of Restoration	Temporary (up to 180 days) acrylic material	Permanent zirconia materials
Construction	Two-piece abutment base with bonded restoration produced via the Straumann CAD/CAM System digital workflow with a 3D printed crown from P pro Crown & Bridge material.	Two-piece abutment base with bonded restoration produced via the Straumann CAD/CAM System digital workflow via local milling by the Straumann M-Series milling machine.
Maximum Angulation	30° controlled in design software	30° controlled in design software
Minimum post-height	4.6 mm	4.55 mm Zolid SHT 4.2 mm Zolid HT
Minimum wall thickness	1.0 mm	0.95 mm Zolid SHT 0.6 mm Zolid HT
Maximum number of pontics	2 pontics	1 pontic - Zolid SHT 2 pontics - Zolid HT
Maximum number of units	6 units	3 units - Zolid SHT 16 units - Zolid HT
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.

Table 3 – Comparison of subject device versus primary predicate device

Feature Comparison:

Indications for Use - The differences between the subject and predicate device are due to the different manufacturing processes and materials. The subject device features an additive 3D printing CAD/CAM procedure while the primary predicate device features a subtractive milling CAD/CAM process. The proposed device uses a 510(k) cleared acrylic resin, Straumann P pro Crown & Bridge (K200039) for temporary use, while the primary predicate uses zirconia milling disks or glass ceramic blocks for permanent use. The intended use for both, production of a crown or bridge on Ti-bases, is substantially equivalent as an endosseous dental implant abutment (CFR 872.3630, Product Code NHA).

Design Specifications – There are differences in the minimum abutment post height and minimum wall thickness between the subject and predicate devices. Fatigue testing of the subject and predicate devices has assured that the subject and predicate device values for these are sufficient for their intended use. The maximum number of units and maximum number of pontics is specified by the material manufacturer and depends on the material. The values used for the subject and predicate devices correspond to the values specified by the respective material manufacturer. The Design Specifications are thus substantially equivalent.

Performance Testing

Dynamic fatigue and static strength 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 that the Straumann Variobases restored with P pro Crown & Bridge constructs are equivalent to the primary predicate and reference devices.

The subject device materials are identical to reference device materials. Biocompatibility tests of the P pro Crown & Bridge material in K200039 (including cytotoxicity, sensitization, irritation) were passed successfully. Therefore, no new issues regarding biocompatibility were raised.

The sterilization process for the Straumann Variobase® 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"*.

Software verification and validation testing was provided for the subject abutment design library to demonstrate effective use with the Straumann CARES Visual CAD software. Software

verification and validation testing was conducted to demonstrate that the restrictions prevent design of the top half component of the two-piece abutment outside of the allowable design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Institut Straumann AG. Non-clinical testing demonstrates that these products are MR Conditional.

Verification of the 3D printer system showed that the design input matched the output, that the process is repeatable and independent of print orientation, build plate location effects, and the effects of material reuse (re-use of leftover material for up to 30 times).

Conclusion

The documentation submitted in this premarket notification has determined that dental restorations designed and manufactured via the Straumann CARES P-Series CAD/CAM System are substantially equivalent to the identified primary and reference predicate devices.