May 15, 2023

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

Re: K222836
Trade/Device Name: Straumann® Variobase® Abutments and n!ce® Zirconia Discs
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, EIH
Dated: February 14, 2023
Received: February 14, 2023

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 -S

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

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)*
K222836

Device Name
Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs

Indications for Use *(Describe)*

Straumann® Variobase® Abutments

The Straumann® Variobase® abutments are prosthetic components 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.

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.

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 manufacturing by a validated milling center.

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.

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)*
K222836

Device Name
Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs

Indications for Use *(Describe)*

Straumann® n!ce® Zirconia discs

Once finalized into a suitable design:

n!ce® Zirconia LT and n!ce® Zirconia HT restorations are indicated for inlays, onlays, veneers, crowns, and bridges up to full arch.

n!ce® Zirconia XT restorations are indicated for inlays, onlays, veneers, crowns, and bridges up to 3 units.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: Institut Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Renate Reiss Associate Director Regulatory Affairs and Compliance Institut Straumann AG Phone number: +41 61 965 1260
Date of Submission:	May 15, 2023

Name of the Device

Trade Names:	Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs
Common Name:	Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	§872.3630
Device Classification:	II
Product Code(s):	Primary product code NHA Secondary product code EIH
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- *K120822 – Straumann Cares Variobase Abutments NNC, Straumann Cares Variobase Abutments RN, Straumann Cares Variobase Abutments WN, ST*

Reference Devices:

- *K170356 - Straumann Variobase Abutments*
- *K190082 - Straumann BLX Variobase Abutment*
- *K200586 - Straumann TLX Implant System*
- *K072569 – Metoxit Cam-Blanks*
- *K170050 – Z-CAD smile*

Device Description

The purpose of this bundled premarket notification is to obtain regulatory clearance for the Straumann subject devices:

- **Straumann® Variobase® Abutments** (NHA)

  A two-piece abutment consisting of a **Variobase** (bottom half) and **ceramic component** (top half),
- **Straumann® n!ce® Zirconia discs** (EIH)

Straumann® Variobase® Abutments

Straumann **Variobase** Abutments are two-piece abutments. The Variobase is the bottom half of the two-piece abutment. The top half of the two-piece abutment is a CAD/CAM designed and manufactured **ceramic component** milled from Straumann n!ce Zirconia (ZrO_2), also subject to this submission as a material suitable for fabrication of the coping or crown that, when bonded to the previously cleared Variobase abutment base, forms a finished dental prosthesis. All digitally designed ceramic components for use with the Straumann Variobase abutments are intended to be sent to Straumann for manufacture at a validated milling center. The following materials are available within the digital workflow for the manufacturing of dental prosthetic restorations: (i) low translucency (LT), (ii) high translucency (HT), and (iii) extra high translucency (XT) n!ce Zirconia. The materials come in various shades (excluding White). . Straumann Variobase abutments are available to interface with the following Straumann dental

implant platforms: Regular Neck (RN), Wide Neck (WN), Regular CrossFit (RC), Wide Base (WB), Regular Base (RB), Narrow TorcFit (NT), Regular TorcFit (RT), Wide TorcFit (WT) and were previously cleared (K120822, K170356, K190082 and K200586).

Straumann® n!ce® Zirconia discs

Straumann n!ce Zirconia (ZrO_2) discs are intended to be milled to produce prosthetic restorations for prepared natural teeth and endosseous dental implant abutments. The material is suitable for use in inlays, onlays, veneers, copings, crowns, and multi-unit restorations. Straumann n!ce Zirconia (ZrO_2) discs will be offered in 3 translucencies: low translucency (LT), high translucency (HT) and extra high translucency (XT).

Intended Use

Straumann® Variobase® Abutments

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

Straumann® n!ce® Zirconia discs

Straumann® n!ce® Zirconia discs are intended to be milled to produce ceramic restorations to restore natural teeth or to be placed on top of abutments.

Indications for Use

Straumann® Variobase® Abutments

The Straumann® Variobase® abutments are prosthetic components 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.

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.

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 manufacturing by a validated milling center.

Straumann® n!ce® Zirconia discs

Once finalized into a suitable design:

n!ce® Zirconia LT and n!ce® Zirconia HT restorations are indicated for inlays, onlays, veneers, crowns, and bridges up to full arch.

n!ce® Zirconia XT restorations are indicated for inlays, onlays, veneers, crowns, and bridges up to 3 units.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables.

Straumann® Variobase® Abutments

Straumann Variobase Abutments are two-piece abutments. The Variobase is the bottom half of the two-piece abutment and is identical to the predicate devices. The top half of the two-piece abutment, the ceramic component milled from Straumann n!ce Zirconia (ZrO_2), differs only in the chemical composition. Minor changes in the chemical composition result in a variation of the shade to achieve the desired esthetic color shade while physical requirements comply to ISO 6872. The indications for use statement slightly differs in wording, where the descriptive term prosthetic components is used interchangeably with two-piece dental abutment or titanium base.

Straumann® n!ce® Zirconia discs

The Straumann n!ce Zirconia discs differ only in the chemical composition of the milling discs. Minor changes in the chemical composition result in a variation of the shade to achieve the desired esthetic color shade while physical requirements comply to ISO 6872. The Indications for Use statement for the subject device is phrased differently but has the same meaning as the reference devices.

Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia discs

510(k) Summary

Feature	Proposed Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	K222836	K120822	K170356	K190082	K200586
Indications for Use	The Straumann® Variobase® abutments are prosthetic components 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. 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. 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 manufacturing by a validated milling center.	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.	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. 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® 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 Variobase prosthetic components directly 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
Ti-base model	•**RN** (Regular Neck) •**WN** (Wide Neck) •**RC** (Regular CrossFit •**RB/WB** (Regular Base/Wide Base) •**WB** (Wide Base) •**NT** (Narrow TorcFit) •**RT** (Regular TorcFit) •**WT** (Wide TorcFit)	•RN •WN •RC	•RN •WN •RC	•RB/WB •WB	•NT •RT •WT

Feature	Proposed Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	K222836	K120822	K170356	K190082	K200586
Coping material **CAD design limits:** **Minimum wall thickness [mm]** **Coping crown angulation [°] (min. GH included in stock devices)**	n!ce Zirconia LT 0.4 mm 30° n!ce Zirconia HT 0.4 mm 30° n!ce Zirconia XT 0.5 mm 30°	Zerion LT 0.4 mm 30°	Zerion ML 0.8 mm 30° Zerion UTML 0.5 mm 30°	Zerion LT, Zerion ML 0.4 mm 30° Zerion UTML 0.5 mm 30°	Zerion LT, Zerion ML 0.4 mm 30° Zerion UTML 0.5 mm 30°
Zirconia class according to ISO 6872	LT and HT 5 XT: 4	Zerion LT 5	Zerion ML 5 Zerion UTML 4	Zerion LT, Zerion ML 5 Zerion UTML 4	Zerion LT, Zerion ML 5 Zerion UTML 4
Flexural strength (MPa)	LT and HT: ≥800 XT: ≥500	Zerion LT ≥800	Zerion ML ≥800 Zerion UTML ≥500	Zerion ML ≥800 Zerion UTML ≥500	Zerion ML ≥800 Zerion UTML ≥500
Workflow/technique	CAD design (CARES Visual) 21 CFR 820 centralized manufacturing (milling)	CAD design (CARES Visual) 21 CFR 820 centralized manufacturing (milling)	CAD design (CARES Visual) 21 CFR 820 centralized manufacturing (milling)	CAD design (CARES Visual) 21 CFR 820 centralized manufacturing (milling)	CAD design (CARES Visual) 21 CFR 820 centralized manufacturing (milling)

Table 1 – Comparison of Straumann® Variobase® Abutments (subject device) versus primary predicate and reference devices

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**K222836**	**K170050**	**K072569**
Indication for use	n!ce® Zirconia LT and n!ce® Zirconia HT restorations are indicated for inlays, onlays, veneers, crowns, and bridges up to full-arch. Zirconia XT restorations are indicated for inlays, onlays, veneers, crowns and bridges up to 3 units.	METOXIT Z-CAD® smile blanks are indicated for the preparation of full ceramic crowns, inlays, onlays, veneers and 3 unit bridges in the anterior area. All white Z-CAD® smile blanks are indicated to be coloured with Z-CAD® Liquid smile-TC The Z-CAD® Liquid smile-TC will be used to dye white pre-sintered zirconia restorations milled from Z-CAD® smile blanks in the dental field.	Metoxit blanks are indicated for use as a substructure for porcelain fused ceramic fixed dental restorations. Limitations are listed in Table 1 **Table 1:** Indications of use and maximum number of pontics. Process chain / Material / Single unit crowns (Anterior, Posterior) / Bridges, number of pontics (Anterior, Posterior) Porous blank is machined to enlarged framework, then sintered and veneered. / TZP-A / X / X / 2 / 2 Al-999 / X / X / 1 / - Dense blank is machined to net-shape framework, then veneered. / TZP / X / X / 2 / 2 TZP-A / X / X / 2 / 2 X indicated; - not indicated; digits show maximum number of pontics. All blanks are solely by or on the order of a dental professional. They are not for use by the general public or over-the-counter.
Zirconia class according to ISO 6872	LT and HT: 5 XT 4	Z-CAD® smile 4	Z-CAD HD and One4All 5
Flexural strength [MPa]	LT and HT ≥800 XT ≥500	METOXIT Z-CAD® smile ≥500	Z-CAD HD and One4All ≥800
Chemical composition	LT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98% Y_2O_3: ≤5.4% Al_2O_3: <0.4% HT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98.0% Y_2O_3: ≤ 7.5% Al_2O_3: ≤ 0.1% XT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98.0% Y_2O_3: ≥7.8% Al_2O_3:≤ 0.1% Other oxides: < 2.0%	XT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98.0% Y_2O_3: $_3$: ≥7.8% Al_2O_3: ≤0.1% Other oxides: < 2.0%	LT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98.0% Y_2O_3: ≤ 6% Al_2O_3: ≤ 0.5% HT $ZrO_2 + HfO_2 + Y_2O_3$: ≥ 98.0% Y_2O_3: ≤7.5 % Al_2O_3: ≤ 0.5 %
Geometry	Ø98.5 mm discs in different heights from 12 - 30 mm	Ø98.5 mm discs in different heights from 10 - 25 mm	Ø98.5 mm discs in different heights from 10 - 25 mm

Table 2 – Comparison of n!ce Zirconia discs (subject device) versus reference devices

Performance Testing

Straumann® Variobase® Abutments

Dynamic fatigue and static strength tests were conducted according to ISO 14801 and 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 two-piece Straumann Variobase Abutments with Straumann n!ce Zirconia are equivalent to the primary predicate and reference devices.

The material of the bottom half of the Variobase Abutments is identical to the primary predicate device, therefore, no new issues regarding biocompatibility were raised. The top half of the two-piece abutment, the ceramic component milled from Straumann n!ce Zirconia (ZrO_2), differs only in the chemical composition, therefore, biocompatibility was confirmed with chemical characterization and in-vitro cytotoxicity according to ISO 10993-5,10993-12, and 10993-18.

The sterilization process for the subject devices as recommended in the labeling was validated according to ISO 17665-1, ISO 17665-2, and applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"*.

Straumann® n!ce® Zirconia discs

The Straumann n!ce Zirconia discs are subject to ISO 6872, Dentistry – Ceramic materials. According to ISO 6872 dental ceramics are classified according to their recommended clinical indication and their mechanical properties. The requirements listed apply as per ISO 6872: Uniformity, freedom from extraneous materials, radioactivity, flexural strength, chemical solubility, CTE (coefficient of thermal expansion) and shrinkage factor.

The Straumann n!ce Zirconia (ZrO_2) discs are similar to the reference devices cleared in K072569 and K170050, therefore, no new issues regarding biocompatibility were raised. The ceramic component milled from Straumann n!ce Zirconia (ZrO_2) discs were evaluated for chemical characterization and in-vitro cytotoxicity according to ISO 10993-5, . 10993-12 and 10993-18.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject devices in 510(k) submission K222836, the Straumann Variobase Abutments and Straumann n!ce Zirconia discs,

are as safe, as effective, and performs as well as the legally marketed primary predicate device and reference devices cleared under K120822, K190082, K170356, 200586, K170050, and K072569. The documentation submitted in this premarket notification demonstrates the subject devices are substantially equivalent to the primary predicate and reference devices.