



December 26, 2024

Institut Straumann AG
% Jennifer Jackson
Sr. Dir. Regulatory & Quality, NAM
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K233252

Trade/Device Name: Straumann CARES Visual and Nova Dental CAD
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: November 27, 2024
Received: November 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

K233252

Device Name

Straumann CARES Visual and Nova Dental CAD

Indications for Use *(Describe)*

Straumann CARES Visual/Nova Implant-borne CAD

The Straumann CARES Visual/Nova Implant-borne CAD software are indicated for the design of two-piece or one-piece abutment components for 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 and CAD software. The system is used to design two-piece abutment CAD/CAM milled copings, crown and bridge restorations to be cemented onto Ti-bases, customized one-piece abutments and bridges/bars to be affixed to the endosseous dental implants using a basal screw. The use of the software requires the user to have the necessary training and domain knowledge in the practice of prosthetic design, as well as training in the use of the software.

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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Straumann CARES Visual and Nova Dental CAD

Summary

510(k) Summary

Submitter: Straumann USA, LLC (on behalf of 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
4052 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: Gordon Dodds
Manager Design Control Quality Management
Etkon GmbH
Phone number: +49 89 309075 291

Date Prepared: December 18, 2024

Name of the Device

Trade Names: Straumann CARES Visual and Nova Dental CAD
Common Name: CAD/CAM Dental Software
Classification Name: Abutment Design Software for Dental Laboratory
Regulation Number: §872.3630.
Device Classification: II
Product Code(s): PNP

Classification Panel: Dental

Predicate Device(s)

Primary Predicate:

- K200100 Abutment Design

Reference Devices:

- *K200586 - Straumann ® TLX Implant System*

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Straumann CARES Visual and Nova Dental CAD

Summary

- *K093113 - ETKON ES1, MODEL 019.0001, ETKON VISUAL*
- *K173968 - Straumann Variobase for Bridge/Bar Cylindrical*

Device Description

Dental CAD Design Software for Implant-borne Restorations

Straumann CARES Visual/Nova is a dental CAD software to create implant-borne restorations. The software employs optical impression files that represent the topographical characteristics of the patient's intraoral situation. The Straumann CARES Visual/Nova software then allows the design of the desired restorations. All implant-borne restorations available in Straumann CARES Visual/Nova software require FDA review and 510(k) clearance. Design specifications ("design envelope"), selectable materials, mouth positions need to be described in these 510(k) submissions. Each restorative solution is defined in a secured design library that provides the CAD software with the design specifications and restrictions for instance, minimum wall thickness, maximum angulation, cementable abutment post height etc. Standard connecting geometries e.g., abutment to implant interface are also defined in the library which cannot be edited by a user. Any dental implant-borne restoration can only be created within the 510(k)-cleared design envelope.

The output of the CAD software is a three-dimensional geometry file which is linked to meta data like material and patient identifier.

All designed implant-borne restorations are intended to be:

- sent to Straumann for manufacturing by a validated milling center, or
- milled on a validated Straumann C series, D series or M series milling machine (only with the CARES Visual software, K171649 and K203456)
- 3D printed as a temporary crown, or temporary bridge (up to 180 days) using P pro Crown & Bridge material on a validated Straumann P series printer (only with the CARES Visual software, K203750)

Straumann CARES Visual/Nova has no patient contact since it is software.

Intended Use

Straumann CARES Visual/Nova Implant-borne CAD

The Straumann CARES Visual/Nova Implant-borne CAD is intended for use as a medical front-end device providing tools for management of models. systematic inspection, acquisition of patient anatomy scans, detailed analysis of data, measurement of device features, control of device

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Straumann CARES Visual and Nova Dental CAD

Summary

dimensions and virtual appliance design of implant-borne prosthetics. The CARES Visual/Nova Implant-borne CAD uses libraries of implant interfaces (containing implant interface geometries, screw geometries, screw-channel design, scanbody dimensions, design limits) to control the design of the prosthetics.

Indications for Use

Straumann CARES Visual/Nova Implant-borne CAD

The Straumann CARES Visual/Nova Implant-borne CAD software are indicated for the design of two-piece or one-piece abutment components for 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 and CAD software. The system is used to design two-piece abutment CAD/CAM milled copings, crown and bridge restorations to be cemented onto Ti-bases, customized one-piece abutments and bridges/bars to be affixed to the endosseous dental implants using a basal screw. The use of the software requires the user to have the necessary training and domain knowledge in the practice of prosthetic design, as well as training in the use of the software.

Technological Characteristics

The underlying scientific concept of the dental CAD design software for implant-borne restorations is to:

- Apply digital imaging tools for visualization of the patient tooth geometries, implant position and orientation (captured through scanbodies) and adjacent/opposing teeth.
- Allow selection of restoration type (Ti-base crown, Ti-base bridge, one-piece abutment, screw-retained bridge/bar).
- Selection of implant interface type from an implant interface library.
- Design prosthetic geometry, with software-controlled material and prosthetic dimension limits.
- Modelling the contact points of the dental restoration with the antagonist teeth.
- Management of patient data.
- Transmission of designs to Straumann central production or (for CARES Visual only) production of design on a validated point-of-care milling or 3D-printing system.

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Straumann CARES Visual and Nova Dental CAD

Summary

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

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	K233252	K200100
RAM	16 GB	8 GB
Operating System	Windows 10 64-bit	Windows 7,8,8.1 or 10 64-bit
Monitor Resolution	1280x800 or similar	1920x1080 pixels
Video Card Memory	1 GB	1 GB
Available HDD Space	500 GB	500 GB
CPU	3.3 GHz Intel Core i5 or equivalent	Intel Core i7 or equivalent

Table 1 – PC/ Laptop hardware requirements comparison - Implant-borne Prosthetic CAD

Feature Comparison of Dental CAD Design Software for Implant-borne Restorations

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Straumann CARES Visual and Nova Dental CAD

Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	K233252	K200100
Indications for use	<p>Straumann CARES Visual/Nova Implant-borne CAD</p> <p>The Straumann CARES Visual/Nova Implant-borne CAD are indicated for the design of two-piece or one-piece abutment components for 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 and CAD software. The system is used to design two-piece abutment CAD/CAM milled copings, crown and bridge restorations to be cemented onto Ti-bases, customized one-piece abutments and bridges/bars to be affixed to the endosseous dental implants using a basal screw. The use of the software requires the user to have the necessary training and domain knowledge in the practice of prosthetic design, as well as training in the use of the software.</p>	<p>Abutment Design is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. Abutment Design is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.</p>
Managing patient and case base data	Yes	Yes
Collection of patient geometries	Yes	Yes
Alignment of patient geometries	Yes	Yes
Measurement of anatomy features	Yes	Yes
Visualize anatomy features	Yes	Yes
Surface scan import from intra-oral scanner	Yes	Yes
3D measurement toolbox	Yes	Yes
Space and contact analysis	Yes	Yes
Analysis occlusion map	Yes	Yes

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Straumann CARES Visual and Nova Dental CAD

Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	K233252	K200100
Management of design limitations	Yes	Yes
Prosthetic design & export	Yes	Yes

Table 2 – Comparison of subject and reference predicate device – Implant-borne Prosthetics CAD

Enhancements of the software, since the reference predicate *K093113* was cleared, have been introduced through the other reference predicates and other implant-borne predicate devices, which include the indications of single tooth Ti-bases, bridges on Ti-bases, one-piece abutments and screw-retained bridges/bars:

- *K200586 - Straumann ® TLX Implant System*
- *K173968 Straumann Variobase for Bridge/Bar Cylindrical*

Performance Testing

Performance Testing – Bench

Software verification and validation testing was provided to demonstrate use of the Straumann CARES Visual and Nova Dental CAD software device for controlling the design specifications and material selections for any prospective compatible abutment design library that undergoes separate 510(k) clearance for the resultant abutment devices.

Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the patient-matched components of the prospective compatible abutment design libraries for the workflow options of customizable two-piece abutments, one-piece abutments, and bridges and bars affixed to the endosseous dental implants from being outside of the allowable design limitations, including representative screenshots under user verification testing. In addition, the software verification and validation testing established that the design limitations and specifications of prospective compatible implant-abutment design libraries are locked and cannot be modified by the end user.

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Summary

Device Software Functions

Software, verification and validation testing was performed in accordance with the FDA Guidance Document "Content of Premarket Submissions for Device Software Functions" (Issued on June 14, 2023).

Conclusion

The documentation submitted in this premarket notification demonstrates that the subject devices are substantially equivalent to the primary predicate and reference devices.