June 3, 2026

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

Re: K260726
Trade/Device Name: Straumann® ProClean™ Cassette (041.800 ; 041.801)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 5, 2026
Received: March 5, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

STEPHEN A. ANISKO -S
Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.06.03 15:20:53 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260726

Device Name
Straumann® ProClean™ Cassette (041.800 ; 041.801)

Indications for Use *(Describe)*

The ProClean™ Cassette is indicated to store and organize Straumann® surgical instruments required during dental implant treatment of the Straumann iExcel™ and Straumann iGuide™ surgical procedures.

The ProClean™ Cassette is indicated to hold and organize the Straumann® surgical instruments during automated cleaning/thermal disinfection, and sterilization in healthcare facilities by healthcare professionals.

The ProClean™ Cassette is only indicated for automated cleaning and thermal disinfection in a washer-disinfector. The ProClean™ Cassette is not indicated to maintain sterility and must be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container.

The Straumann ProClean™ Cassette has been validated for the following maximum load (including instruments and cassette): Max. 1223 grams.

Recommended sterilization time (exposure time at the sterilization temperature) and drying time:

Method	Conditions	Drying time
Moist Heat (Autoclave) Fractionated vacuum	132 °C (270 °F) for 4 min	30 min

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.

Traditional 510(k) Submission

Straumann ProClean™

K260726 510(k) Summary

510(k) Summary
Submitter's Contact Information

Submitter: Straumann USA, LLC
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Andover, MA 01810
Registration No.: 1222315 Owner/Operator No.: 9005052

On behalf of:
Institut Straumann AG
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Prepared By: Mohammed Ghaleb
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Phone number: +41619651667

Date Prepared: June 3, 2026

Name of the Device

Trade Names:	Straumann® ProClean™ Cassette (041.800 ; 041.801)
Common Name:	Sterilization wrap containers, trays, cassettes & other accessories
Classification Name:	Sterilization wrap
Regulation Number:	880.6850
Device Classification:	II
Product Code:	KCT

Traditional 510(k) Submission

Straumann ProClean™

K260726 510(k) Summary

Predicate Device(s)

- K191475 - Nobel Biocare N1 PureSet Tray, Nobel Biocare N1 PureSet Plate, Prosthetic PureSet Tray, Prosthetic PureSet Plate

Reference Device:

- K191522 - Straumann Modular Cassette

Device Description:

The Straumann ProClean™ Cassette is designed as a reusable wash and sterilization cassette system and for the storage of surgical and prosthetic instruments of the Straumann® Dental Implant System. In addition to its core functionality, the trays of the Straumann ProClean™ Cassette features distinct color-coded grommets and instrument pictograms to facilitate the surgical procedure and the correct use and positioning of the instruments.

Indications for Use:

The ProClean™ Cassette is indicated to store and organize Straumann® surgical instruments require during dental implant treatment of the Straumann iExcel™ and Straumann iGuide™ surgical procedures.

The ProClean™ Cassette is indicated to hold and organize the Straumann® surgical instruments during automated cleaning/thermal disinfection, and sterilization in healthcare facilities by healthcare professionals.

The ProClean™ Cassette is only indicated for automated cleaning and thermal disinfection in a washerdisinfector. The ProClean™ Cassette is not indicated to maintain sterility and must be used in conjunction with a legally marketed, validated sterilization pouch or a sterilization container.

The Straumann ProClean™ Cassette has been validated for the following maximum load (including instruments and cassette): Max. 1223 grams.

Recommended sterilization time (exposure time at the sterilization temperature) and drying time:

Method	Conditions	Drying time
Moist Heat (Autoclave) Fractionated vacuum	132 °C (270 °F) for 4 min	30 min

Technological Characteristics

The technological characteristics of the subject devices are compared to the predicate device in the following table:

FEATURE	Subject Device K260726	Predicate Device K191475	Reference Device K191522	COMPARISON DISCUSSION
Indications for Use	The ProClean™ Cassette is indicated to store and organize Straumann® surgical instruments require during dental implant treatment of the Straumann iExcel™ and Straumann iGuide™ surgical procedures. The ProClean™ Cassette is indicated to hold and organize the Straumann® surgical instruments during automated cleaning/thermal disinfection, and sterilization in healthcare facilities by healthcare professionals. The ProClean™ Cassette is only indicated for automated cleaning and thermal disinfection in a washerdisinfector. The ProClean™ Cassette is not indicated to maintain sterility and must be used in conjunction with a legally	The Nobel Biocare PureSet Trays are used in healthcare facilities to store and organize Nobel Biocare surgical/prosthetic instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The Nobel Biocare PureSet Trays are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst- case PureSet Tray included surgical/prosthetic instruments such as torque wrenches, implant drivers, direction indicators, drills, screw taps, screw driver and irrigation needles. The PureSet Trays were validated for a	Straumann® Modular Cassette is used in healthcare facilities to organize, enclose, sterilize, transport and store Straumann instruments between surgical uses. Straumann® Modular Cassette is not intended to maintain sterility on its own, but is intended to be used in conjunction with a legally marketed, validated sterilization double pouch to maintain the sterility of the enclosed devices. The Straumann® Modular Cassette has been validated for the following maximum loads: • Module A 400g • BCC Maximum permissible stack BCC 611g The A module is intended to be sterilized individually, without stacking with other modules.	Identical

	marketed, validated sterilization pouch or a sterilization container. ProClean™ Cassette sterilization parameters: The Straumann ProClean™ Cassette has been validated for the following maximum load (including instruments and cassette): Max. 1223 grams. Recommended sterilization time (exposure time at the sterilization temperature) and drying time: For the United States and Canada: Moist Heat (Autoclave) Fractionated vacuum 132°C (270°F) for 4 min 30 min drying time	maximum load of 1635 grams (Trefoil PureSet Tray), 1082 grams (NobelActive/ NobelPar allel CC PureSet Tray), 945 grams (NobelReplace CC PureSet Tray), 454 grams (Nobel Biocare N1™ PureSet) and 486 grams (Prosthetic PureSet).	The B and C module are intended to be sterilized individually, or by stacking the B module on top of C module bases. The maximum permissible stack for sterilization is one B module on top of two C module bases. The B module lid and C module lid could be used to enclose an ultrasonic mat (Art. No. 041.774) for ultrasonic bath cleaning used instruments. Only use the following sterilization parameters: • Fractionated vacuum: 132°C (270 °F) for 4 minutes with 30 minutes drying time	
Product Code	KCT	KCT	KCT	Identical
Design	Stainless Steel cassette, Silicone grommets	Single level tray with grommets and a basket for holding tooling in specific locations and covering lid (without handle).	Plastic modules, trays and lids	Same material
Materials	ProClean Cassette: - Stainless steel (1.4301, 1.4305, 1.4310) - Silicone (grommets)	PureSet Tray - Stainless steel construction (1.4301,1.4303, 1.4310, 1.4024)	Polyphenylsulfone Silicone Stainless steel (lid hinge)	Identical

		- PEEK grommets and storage sleeves - PEEK mini tray locks - Silicone elastomer feet PureSet Tray Plate Aluminum construction with anodization		
Materials compatible with sterilization method	Yes	Yes	Yes	Identical
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Identical
Reusable	Yes	Yes	Yes	Identical
Sterilization method	Moist heat (steam)	Moist heat (steam)	Moist heat (steam)	Identical
Cycles and parameters	Fractionated vacuum 132°C (270 °F) for 4 minutes with 30 minutes drying time	Fractionated vacuum 132°C (270 °F) for 4 minutes with 20 minutes drying time Gravity Displacement 132°C (270 °F) for 15 minutes 30 minutes drying time	Fractionated vacuum 132°C (270 °F) for 4 minutes with 30 minutes drying time	Identical drying time identical to Reference Device
Sterile barrier	FDA cleared sterilization pouch or metal sterilization container	FDA cleared sterilization wrap/pouch	FDA cleared sterilization wrap/pouch	Equivalent; A validation was performed with both sterile barriers.

The subject and predicate device share the following characteristics:

- indications for use
- design
- identical sterilization method and similar sterilization parameters
- reusable

The subject device is technologically different from the predicate device as follows:

- drying time
- weight
- Size

Nevertheless, the related performance is proven through testing.

Summary of Non-Clinical Testing

The performance during multiple reprocessing steps for the ProClean Cassette, 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"*.

The test results demonstrate that the ProClean Cassette is similar to the predicate device.

Cleaning and Sterilization Validation

The subject device, i.e. Straumann® ProClean Cassettes system, is intended to store and organize Institut Straumann AG surgical instruments and components during cleaning, disinfection, sterilization, and implant treatment. The cassette system is a multiple-use device and must be cleaned, disinfected, and sterilized prior to use at the patient. The sterilization procedures reflect the FDA guidance document, "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015*"

Cleaning validation was done under worst case conditions in accordance with ISO 17664:2021 and AAMI ST98:2022.

The sterilization parameters have been validated in accordance with ISO 17665:2024, to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. In addition to the SAL validation, dry time was validated using full cycle parameters.

Biocompatibility

The biological assessment of the Straumann® ProClean Cassettes was performed according to ISO 10993-1:2021 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and the biocompatibility evaluation flow chart according to the FDA Guidance document "*Use of International Standard ISO 10993-1:2020, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff.*

The results show that none of the test items after 1x, 50x and 100x reprocessing elicited a cytotoxic response. All results are above the limit of 70% viability of cells (see ISO 10993-5 and Table 1). This means that the test items do not release substances in cytotoxic concentrations. In this study under the given conditions no leachable substances were released in cytotoxic concentrations from the test item.

Therefore, the Straumann ProClean Cassette is considered biologically safe for its intended use according to ISO 10993-1 and FDA's guidance document on ISO 10993-1**.**

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K191475).