July 29, 2021

Straumann USA, LLC
Jennifer Jackson
Director, Regulatory Affairs
60 Minuteman Rd
Andover, Massachusetts 01810

Re: K203753
Trade/Device Name: Straumann Surgical Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 25, 2021
Received: June 28, 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 Clarence W. Murray, III, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K203753

Device Name

Straumann® Surgical Cassettes

Indications for Use *(Describe)*

The Straumann Cassettes are used to organize, store, sterilize and transport surgical instruments and auxiliaries between and during surgical uses. They are indicated to be used in healthcare facilities by healthcare professionals.

The Straumann Cassettes are to be enclosed in FDA cleared sterilization pouches in two layers to maintain the sterility of the enclosed devices using the following sterilization parameters: pre-vacuum steam exposure at 132°C (270° F) for 4 minutes, 30 minutes drying time.

The Straumann Cassettes have been validated for a maximum load of 1005 grams for the Surgical Cassettes, 2007 grams for the Osteotome Cassettes, 283 grams for the Bone Block Fixation Cassette and 65 grams for the Screw Container, including cassette and instruments.

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 (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
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 & Alternate Contact:	Chanrasmey White, MS Regulatory Affairs Specialist Straumann, USA, LLC
Date of Submission:	July 29, 2021

Name of the Device

Trade Names:	Straumann® Surgical Cassettes
Common Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Number:	§880.6850
Device Classification:	II
Product Code(s):	KCT
Classification Panel:	General Hospital

Predicate Device(s)

Primary Predicate:

- K180791 – Straumann BLX Surgical Cassette (Institut Straumann AG)

K203753 – Traditional 510(k)

Straumann® Surgical Cassettes

510(k) Summary

Reference Devices:

- K191522 – Straumann Modular Surgical Cassette (Institut Straumann AG)

Device Description

Straumann® Surgical Cassettes are designed to hold various dental surgical drills and tools in order to organize, sterilize and protect the instruments that are sterilized by the healthcare provider. The subject devices consist of reusable rigid containers, comprising of a case bottom (base), a removable inner tray base (tray), and tray lid (lid). The case base, tray base, and tray lid are designed to be integrated into a single unit which contains and protects the interior components during sterilization and subsequent storage. The tray lid latches to the case bottom is designed to secure the kit into a single unit. The kits are perforated to allow for penetration of the moist heat (steam) sterilant and require the use of an FDA-cleared wrap to maintain sterility. To facilitate the surgical procedure and the correct use and positioning of the instruments, the trays and modules have instrument pictograms and/ or color-coded workflows printed on the surface. Surgical and prosthetic instruments of the Straumann® Dental Implant System intended to be placed in the Straumann® Surgical Cassettes are used for bed preparation, placement, maintenance and explanation of the implants from Straumann® Dental Implant System. These devices are all Class I exempt as described in 21 CFR 872.3980 (Endosseous dental implant accessories) and are not subject devices of this submission.

In addition, the Straumann Screw Container is included in this submission. The Straumann Screw Container is used for storing and sterilizing closure screws and healing caps. All the closure screws and healing caps that may be contained in the Screw Container

are cleared Class II devices according to 21 CFR 872.3630 (Endosseous dental implant abutment) and are not subject devices of this submission.

Intended Use

The Straumann Cassettes are intended to store, organize and reprocess surgical instruments and auxiliaries of the Straumann® Dental Implant System during implant/prosthetic treatment and sterilization.

Indications for Use

The Straumann Cassettes are used to organize, store, sterilize and transport surgical instruments and auxiliaries between and during surgical uses. They are indicated to be used in healthcare facilities by healthcare professionals.

The Straumann Cassettes are to be enclosed in FDA cleared sterilization pouches in two layers to maintain the sterility of the enclosed devices using the following sterilization parameters: pre-vacuum steam exposure at 132°C (270º F) for 4 minutes, 30 minutes drying time.

The Straumann Cassettes have been validated for a maximum load of 1005 grams for the Surgical Cassettes, 2007 grams for the Osteotome Cassettes, 283 grams for the Bone Block Fixation Cassette and 65 grams for the Screw Container, including cassette and instruments.

Technological Characteristic Comparison

The subject and predicate device share the following characteristics:

- Equivalent indications for use
- Equivalent design
- Identical sterilization method
- Equivalent sterilization parameters
- Reusable

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

- Materials (the only part of the cassette made out of stainless steel is the lid hinge)
- Vent-to-Volume ratio
- Drying time

The technological characteristics of the subject devices are compared to the predicate devices in Table 1.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	COMPARISON
K Number	K203753	K180791	K191522	
Indications for Use	The Straumann Cassettes are used to organize, store, sterilize and transport surgical instruments and auxiliaries between and during surgical uses. They are indicated to be used in healthcare facilities by healthcare professionals. The Straumann Cassettes are to be enclosed in FDA cleared sterilization pouches in two layers to maintain the sterility of the enclosed devices using the following sterilization parameters: pre-vacuum steam exposure at 132°C (270º F) for 4 minutes, 30 minutes drying time. The Straumann Cassettes have been validated for a maximum load of 1005 grams for the Surgical Cassettes, 2007 grams for the Osteotome Cassettes, 283 grams for the Bone Block Fixation Cassette and 65 grams for the Screw Container, including cassette and instruments.	The Straumann BLX Cassette is used in healthcare facilities to organize, enclose, cleaning, sterilize, transport, and store medical devices between surgical uses. The BLX Cassette is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated sterilization wrap. The BLX Cassette has been validated for a maximum load of 300 grams, including cassette and instruments. Sterilization parameters: Pre-vacuum steam: 132°C (270º F) for 4 minutes with 20 minutes drying time.	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. 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	Similar
Product Code	KCT	KCT	KCT	Same

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	COMPARISON
K Number	K203753	K180791	K191522	
Design	Reusable rigid container, case bottom (base), a removable inner tray base (tray), and tray lid (lid).	Plastic tray and lid	Plastic modules, trays and lids	Similar
Materials	Polyphenylsulfone (Radel 5000) Tecapro MT, Propylux Silicone Stainless Steel EUROPLEX® PPSU 99050 GT, grey PP HS2 WHV200 WM, white	Polyphenylsulfone (Radel R5000) Silicone	Polyphenylsulfone Silicone Stainless Steel	Similar
Materials compatible with sterilization Method	Yes	Yes	Yes	Same
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	Same
Reusable	Yes, up to 100x	Yes, up to 100x	Yes, up to 100x	Same
Sterilization method	Moist heat (steam)	Moist heat (steam)	Moist heat (steam)	Same
Cycles	Pre-vacuum	Pre-vacuum	Fractionated vacuum	Same as K180791
Parameters	Pre-Vacuum: 132º C (270º F) for 4 minutes; 30 minutes drying time	Pre-Vacuum: 132º C (270º F) for 4 minutes; 20 minutes drying time	Fractionated vacuum: 132°C (270 °F) for 4 minutes; 30 minutes drying time	Same as K180791
Sterile barrier	FDA cleared sterilization pouch	FDA cleared sterilization pouch	FDA cleared sterilization pouch	Same
Biocompatibility	The Biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate that the subject devices are non-cytotoxic.	The Biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate that the subject devices are non-cytotoxic.	The Biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate that the subject devices are non-cytotoxic.	Same

Table 1 – Comparison Matrix

Performance Testing

The performance during multiple reprocessing steps for the Straumann® Surgical Cassettes, 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 worst-case cassettes were tested for performance based on critical impact factors including weight, vent to volume ratio and worst-case instruments to be contained. The summary of testing performed is provided in Table 2.

Type of Testing	Purpose	Acceptance Criteria	Result
Manual Cleaning Validation (AAMI TIR 30:2011)	Evaluate and validate the manual cleaning of the subject devices	• No visible soil • Amount of protein per sample <100 µg • Amount of protein/cm^2 <3.0 µg/cm^2 • Amount of hemoglobin/cm^2 <2.2 µg/cm^2	Pass
Automated Cleaning Validation (AAMI TIR 30:2011)	Evaluate and validate the automated cleaning of the subject devices	• No visible soil • Amount of protein per sample <100 µg • Amount of protein/cm^2 <3.0 µg/cm^2 • Amount of hemoglobin/cm^2 <2.2 µg/cm^2	Pass
Sterilization Validation (ISO 17665-1:2006/(R)2013)	Validate a sterilization cycle and drying time of the subject devices	• SAL ≤10^{-6} using the biological indicator (BI) overkill method	Pass
Reprocessing of Medical Devices in a Health Care Setting	Life Cycle (simulated use) testing after 100 cleaning and sterilization cycles	• Test samples must withstand 100 cycles of use (cleaning, sterilization, and functional tests) without compromising function	Pass

Biocompatibility (ISO 10993-5)	Cytotoxicity Testing	• Viability of cultures treated with test extracts >70%	Pass

Table 2 – Performance testing summary

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K203753, Straumann Surgical Cassettes, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180791 and K191522.