Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs & Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K180791
Trade/Device Name: Straumann BLX Surgical Cassette
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 27, 2018
Received: March 27, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180791

Device Name
Straumann BLX Surgical Cassette

Indications for Use *(Describe)*

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 (270° F) for 4 minutes with 20 minutes drying time.

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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1 510(k) Summary

1.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

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Contact Person:	Jennifer M. Jackson, MS
Preparer / Alternate Contact:	Ana Carolina Martins Vianna
Preparer / Alternate Contact:	Viviana Horhoiu
Date of Submission:	June 20, 2018

1.2 Name of the Device

Trade Names:	Straumann® BLX Surgical Cassette
Common Name:	BLX Surgical Cassette
Classification Name:	Sterilization wrap
Regulation Number:	21 CFR 880.6850
Classification:	Class II
Product Codes:	KCT

1.3 Predicate Device(s)

Primary Predicate:

- K163600 – Kit Boxes and Kit Plates, Nobel Biocare AB

Reference Devices:

- K160730 – Instrument kits, Anthogyr

1.4 Device Description

The BLX Surgical Cassette is a container composed of three main components: a lid, a cassette base and a tray, all made of polyphenylsulfone (Radel R5000). The base and the tray have silicone rubber grommets to hold the instruments. The base and tray are printed to indicate the surgical workflow and the position of the instruments within the cassette.

New surgical and prosthetic instruments have been developed to accommodate the new Straumann® BLX Implant System, a line of endosseous dental implants and abutments that are not subject devices to this submission. These new instruments are used for implant bed preparation and abutment removal (if necessary after placement). These devices are all Class I exempt as described in 21 CFR 872.3980 (Endosseous dental implant accessories) and are not subject devices to this submission. The cassette, along with a complete load of instruments, weights 300 g.

1.5 Indications for Use

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.

1.6 Comparison of Technological Characteristics

The subject and primary predicate devices share the following characteristics:

- Intended Use
- Design
- Sterilization Method and Parameters
- Reusable

The subject devices are technologically different from the primary predicate devices as follows:

- Material
- Vent / volume ratio

Nevertheless, the technological characteristics were evaluated through non-clinical testing.

Table 1 provides a comparison matrix of the features of primary predicate, reference and subject devices:

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

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	Subject Device	**K163600 Kit Boxes and Kit Plates**	**K160730 Instrument Kits**
Intended Use	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 Nobel Biocare Kit Boxes are used in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses. The Nobel Biocare Kit Boxes are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.	The instrument kits are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider. The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility.
Product Code	KCT	KCT	KCT
Design	Plastic tray and lid	Kit Box – Plastic tray and lid Kit Plate – Silicone grommets and tool holders	Plastic tray and lid
Materials	• Polyphenylsulfone (Radel R5000) • Silicon	• Aluminum • Polymer • Silicon	• Polyphenylsulfone (Radel R5000, Radel R5100) • Medical grade silicone • Stainless steel
Materials compatible with Sterilization Method	Yes	Yes	Yes
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
Enclosing feature	Silicone grommets	Silicone grommets	Silicone grommets
Reusable	Yes	Yes	Yes
Sterilization Method	Moist heat (steam)	Moist heat (steam)	Moist heat (steam)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	Subject Device	**K163600 Kit Boxes and Kit Plates**	**K160730 Instrument Kits**
Cycles	Pre-vacuum	Gravity-Displacement Pre-vacuum	Pre-vacuum
Parameters	Pre-Vacuum: 132º C (270º F) for 4 minutes; 20 minutes drying time	Pre-Vacuum: Temp 270º F Exposure Time: 4 min Pre-vacuum: 3 times < 60 mbar Drying Time: 30 min Cooling Time: 10 minutes at room Temperature Gravity: Temp 270º F Exposure Time: 15 min Drying Time: 30 min Cooling Time: 10 minutes at room temperature	Pre-Vacuum: 134 °C during 3 min, 16 minutes drying time
Sterile Barrier	FDA cleared sterilization pouch	FDA cleared sterilization wrap/pouch	FDA cleared sterilization pouch
Vent/volume ratio	0.054 in^2/in^3	Information not available.	0.049 in^2/in^3

Table 1 – Comparison of subject device versus predicate device

1.7 Non-Clinical Testing

The performance during multiple reprocessing steps for the Straumann BLX Surgical 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*".

Cleaning and Sterilization Validation

The subject device is a multiple-use device provided non-sterile which needs to be end user sterilized. The cleaning and 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*".

Both manual and automated cleaning methods were validated and demonstrated the effectiveness of the recommended manual and automated cleaning processes.

Sterilization Validation

The sterilization parameters have been validated to a sterility assurance level (SAL) of $\geq 10^{-6}$ using the biological indicator (BI) overkill method according to ANSI/AAMI/ISO 17665-1 "*Sterilization of health care products - Moist heat - Part1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*". In addition to the SAL validation, dry times were validated using full cycle parameters according to AAMI TIR12:2010 "*Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*".

Biocompatibility

The biological assessment of the BLX Cassette was performed according to ISO 10993-1:2009 "*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, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*".

The following biocompatibility studies were conducted:

- *In vitro* cytotoxicity according to ISO 10993-12 and ISO 10993-5
- Chemical characterization according to ISO 10993-12 and 10993-18

Results of conducted studies based upon the biological safety profile of the BLX surgical cassette show that they are biocompatible for their intended use.

1.8 Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate device, cleared under K163600 under regulation 21 CFR 880.6850, product code KCT.