March 4, 2022

Dentsply Sirona Inc.
Courtney Clark
Sr. Director, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K212281
Trade/Device Name: Surgical Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 1, 2022
Received: February 2, 2022

Dear Courtney Clark:

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,

Clarence W. Murray, III, Ph.D.
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)*
K212281

Device Name
Surgical Trays

Indications for Use *(Describe)*
The Surgical Trays are intended for organizing, sterilizing and storing of instruments.
The Surgical Trays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Sterilization parameters:
Pre-Vacuum Steam at 132 °C (270 °F) for 4 min with a 20 minutes dry time

The tested Surgical Tray represents the worst-case validated load of 513.7g.
Do not exceed the following maximum load:

Product name	Article Number	Max Load (g)	Vent to Volume Ratio (in^{-1})
OmniTaper Surgical Tray	68015282	513.7	0.033
PrimeTaper Surgical Tray	68015321	513.7	0.033

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Dentsply Sirona Inc.
221 West Philadelphia Street, Suite 60W
York, PA 17401

510(k) SUMMARY
Surgical Trays
K212281

5.1 Submitter Information:

Dentsply Sirona Inc.
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Courtney Clark
Telephone Number: 248-895-4379
Fax Number: 717-849-4343
Email: corporate-ra@dentsplysirona.com

Date Prepared: March 4, 2022

5.2 Device Name:

- Proprietary Name: Surgical Trays
- Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- CFR Number: 21 CFR 880.6850
- Device Class: Class II
- Product Code: KCT

5.3 Predicate Device:
The predicate device identified is the following:

Predicate Device Name	**510(k)**	**Company Name**
Straumann BLX Surgical Cassette	K180791	Institut Straumann AG

5.4 Device Description:

The proposed Surgical Tray is a reusable perforated container that is intended to store and organize the instruments needed before, during and after implant surgery as well as holding instruments during sterilization.

The Surgical Tray is a container composed of three main components: a lid, a base and an overlay, all made of polyphenylsulfone (Radel R5000). The overlay has co-molded silicone tooling supports. The base has silicone rubber grommets to hold instruments. The base and overlay are custom printed to indicate the surgical workflow and the position of the instruments within the tray for the different product lines.

The proposed Surgical Tray is available in one size with outer dimensions of 7.3 x 5.5 x 2.4 inches and offered in 2 inner tray configurations with varied instrument loads, see Table 5.1.

Table 5.1- Surgical Tray configurations				
Product name	**Model number**	**Max no of instruments**	**Max load (g)**	**Vent to volume ratio (in^{-1})**
OmniTaper Surgical Tray	68015282	51	513.7	0.033
PrimeTaper Surgical Tray	68015321	45	513.7	0.033

5.5 Indications for Use

The Surgical Trays are intended for organizing, sterilizing and storing of instruments.

The Surgical Trays are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Sterilization parameters:
Pre-vacuum Steam at 132°C (270°F) for 4 minutes with a 20 minutes dry time.
The tested Surgical Tray represents the worst case validated load of 513.7g.

Product name	**Article number**	**Max load (g)**	**Vent to volume ratio (in^{-1})**
OmniTaper Surgical Tray	68015282	513.7	0.033
PrimeTaper Surgical Tray	68015321	513.7	0.033

5.6 Comparison of Technological Characteristics

An overview of the similarities and differences between the proposed and predicate device is given in Table 5.2. The proposed Surgical Tray and the predicate device, Straumann BLX Surgical Cassette (K180791), have the same intended use, same sterilization method and parameters, are made of the same materials and have a similar design. The vent to volume ratio for the proposed Surgical Tray is 0.033 in^{-1} while the predicate vent to volume ratio is 0.054 in^{-1}. The proposed Surgical Tray has a lower vent to volume ratio.

When compared to the predicate device, the proposed Surgical Tray can hold more instruments and has a larger maximum sterilization load. The maximum sterilization load for the proposed Surgical Tray is 513.7g, while the predicate's maximum sterilization load is 300g. Sterilization validation was performed to support the sterilization load of the proposed Surgical Tray and has been validated to SAL of 10^{-6}.

<table>
<tr><th colspan="4">Table 5.2: Similarities and Differences between the proposed and predicate devices</th></tr>
<tr><th>Elements</th><th>Proposed Device
Surgical Tray</th><th>Predicate Device
Straumann BLX Surgical Cassette (K180791)</th><th>Comparison</th></tr>
<tr><td>Manufacturer</td><td>Sirona Dental Systems GmbH</td><td>Institut Straumann AG</td><td>Different manufacturer</td></tr>
<tr><td>Indications for use</td><td>The Surgical Trays are intended for organizing, sterilizing and storing of instruments.

The Surgical Tray is not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Sterilization parameters:
Pre-vacuum Steam at 132°C (270°F) for 4 minutes with a 20 minutes dry time.

The tested Surgical Tray represents the worst case validated load of 513.7g.

Do not exceed the following maximum load:
<table>
<tr><th>Product name</th><th>Article number</th><th>Max load(g)</th><th>Vent to volume ratio (in^{-1})</th></tr>
<tr><td>OmniTaper Surgical Tray</td><td>68015282</td><td>513.7</td><td>0.033</td></tr>
<tr><td>PrimeTaper Surgical Tray</td><td>68015321</td><td>513.7</td><td>0.033</td></tr>
</table></td><td>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</td><td>Similar indications but the proposed Surgical Tray is not indicated for cleaning device.
The proposed device is intended to be used with a validated sterilization pouch.</td></tr>
<tr><td>Product code</td><td>KCT</td><td>KCT</td><td>Same</td></tr>
</table>

Table 5.2: Similarities and Differences between the proposed and predicate devices			
Elements	**Proposed Device Surgical Tray**	**Predicate Device Straumann BLX Surgical Cassette (K180791)**	**Comparison**
General Design	Plastic tray with locking lid. Co-molded silicone and silicone grommet supports	Plastic tray and lid	Similar, both trays are designed to hold instruments for implant surgery and sterilization and consist of a plastic box with an insert adapted for the specific surgical procedure. The inserts have silicone holders for instruments.
Dimensions	7.3 in x 5.5 in x 2.4 in	5.6 in x 3.9 in x 2.4 in	Similar
Material	Base – Radel 5000 Lid – Radel 5000 Overlay – Radel 5000 Tooling support - Silicone	Radel 5000 Silicone	Same
Air permeance	Yes, allow moist heat (steam) penetration to achieve sterilization	Yes, allow moist heat (steam) penetration to achieve sterilization	Same
Mass of maximum sterilization load	OmniTaper Surgical Tray: 513.7g PrimeTaper Surgical Tray: 513.7g	300g	Different
Vent to volume ratio	OmniTaper Surgical Tray: 0.033 in^{-1} PrimeTaper Surgical Tray: 0.033 in^{-1}	0.054 in^{-1}	Different
Sterility	Non-sterile	Non-sterile	Same
Sterilization Method	Moist heat (steam)	Moist heat (steam)	Same
Sterilization Parameters	Pre vacuum, At 132°C for 4 minutes with a 20 minutes dry time	Pre vacuum At 132°C for 4 minutes with a 20 minutes dry time	Same
Sterile barrier	FDA cleared sterilization pouch	FDA cleared sterilization pouch	Same
Reusable	Yes	Yes	Same

5.7 Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon, including acceptance criteria and set specifications in test methodology and standards, are summarized below:

Test Name	Test Methodology	Purpose	Acceptance Criteria	Results
Sterilization cycle validation	• ANSI/AAMI/ISO 17665-1:2006/(R)2013 • ISO 17665-2:2009	To validate that the trays can be sterilized via moist-heat sterilization as specified on labeling (132° C for 4 minutes)	Sterility assurance level (SAL) of $\leq 10^{-6}$	Pass
Drying validation	• AAMI TIR12: 2020 • ANSI/AAMI/ISO 17665-2:2009	To validate that the trays can be dried as specified on labeling (drying time of 20 minutes)	No visible moisture ≤ 3% weight gain of packaging and absorbable materials	Pass
Reprocessing of trays (cleaning and sterilization)	Internal Test Method	To confirm that the trays can be reprocessed as specified on labeling (up to 200 reprocessing cycles without any signs of abrasion)	No signs of flush rust, rust corrosion, deformation or damage	Pass
Simulated use of trays	Internal Test Method	To confirm that the trays can withstand simulated use of up to 1,500 repeated reposition cycles	-No significant wear of the holders -The instruments must have safe seating in the holders after the shake test	Pass
Cytotoxicity	ISO 10993-5:2009	To confirm that no cytotoxic substances are released after reprocessing of the trays	Inhibition of cell proliferation must be at or below 30% compared to untreated cultures	Pass

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 follow 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".

The sterilization parameters were validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator overkill method according to ANSI/AAMI/ISO 17665-1:2006/(R)2013 *(Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices)* and ISO 17665-2:2009 *(Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1).*

In addition to the SAL validation, dry times were validated to meet the requirements of the guidance outlined in AAMI TIR12:2020 *(Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers)*, as required, and ANSI/AAMI/ISO 17665-2:2009.

Usability wear study
Non-clinical performance and wear testing of the proposed Surgical Tray was performed through

simulated use testing. The Surgical Tray was filled with instruments and subjected to 200 cleaning cycles and 200 sterilization rounds.

In addition, simulated use testing was performed to simulate 1,500 repeated repositioning of relevant instruments in the holder, after which the trays were subjected to a shake test.

There were no signs of damage or alterations after testing and the instruments were safely seated in the holders. The automated cleaning and sterilization method were validated and demonstrated the effectiveness of the recommended process as stated in the Instructions for Use.

Biocompatibility
Biocompatibility evaluation assessment for the Surgical Tray was performed according to ISO 10993-1:2018 *(Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process).*

The biocompatibility studies conducted were in vitro cytotoxicity according to ISO 10993-5:2009 *(Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity).* The test results confirm that the Surgical Trays are biocompatible for their intended use.

5.8 Conclusion

The conclusions drawn from the non-clinical test data support that the proposed Surgical Trays are as safe, as effective and perform as well as or better than the legally marketed predicate device Straumann BLX Surgical Cassette (K180791).