Dentsply Sirona
Courtney Clark
Senior Director of Regulatory Affairs, Corporate
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401
USA

May 3, 2022

Re: K220791
Trade/Device Name: Surgical and Prosthetic Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap containers, Trays, Cassettes & Other Accessories
Regulatory Class: Class II
Product Code: KTC
Dated: March 16, 2022
Received: March 18, 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,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K220791

Device Name

Surgical and Prosthetic Trays

Indications for Use *(Describe)*

The Surgical and Prosthetic Trays are intended for organizing, sterilizing and storing of instruments.
The Surgical and Prosthetic 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 minute dry time
Do not exceed the worst-case validated maximum load:

Product name	Article Number	Maximum Load (g)	Vent to Volume Ratio (in^{-1})
OmniTaper Surgical Tray	68015282	513.7	0.033
PrimeTaper Surgical Tray	68015321	513.7	0.033
PrimeTaper Surgical Tray GS Medium	68017268	563.5	0.033
OmniTaper Surgical Tray GS	68017203	563.5	0.033
Bone Reamer Tray	68015280	271.9	0.046
Prosthetic Tray	68015288	271.9	0.046

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Surgical and Prosthetic Trays, K220791

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: May 3, 2022

Device Name:

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

Predicate Device:

The predicate device identified is the following:

Predicate Device Name	**510(k)**	**Company Name**
Surgical Trays	K212281	Dentsply Sirona

Device Description:

The proposed Surgical and Prosthetic Trays are reusable perforated containers that are intended to store and organize the instruments needed before, during and after implant surgery and the prosthetic procedure as well as hold instruments during sterilization.

The Trays are containers composed of three main components: a lid, a base and an overlay, which are all made of polyphenylsulfone (Radel R5000NT). The trays have co-molded silicone tooling supports and silicone rubber grommets to hold instruments. The base and overlay are custom printed to indicate the guided surgery or prosthetic procedure workflow and the position of the instruments within the tray for the different product lines.

The proposed Surgical and Prosthetic Trays are available in two tray sizes. The Surgical trays are available in medium size with outer dimensions of 7.3 x 5.5 x 2.4 inches and the Prosthetic trays are available in small size with outer dimensions of 5.4 x 3.9 x 2.4. Each tray size is offered in 2 inner tray configurations with varied instrument loads, see Table 1.

510(k) SUMMARY
Surgical and Prosthetic Trays, K220791

Table 1: Surgical and Prosthetic Trays configurations

Product name	Part number	Tray size	Max no of instruments	Max load(g)	Vent to volume ratio(in^{-1})
PrimeTaper Surgical Tray GS Medium	68017268	Medium	55	563.5	0.033
OmniTaper Surgical Tray GS	68017203	Medium	56	563.5	0.033
Bone Reamer Tray	68015280	Small	24	271.9	0.046
Prosthetic Tray	68015288	Small	22	271.9	0.046

Indications for Use

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

The Surgical and Prosthetic 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 minute dry time.
Do not exceed the worst-case validated maximum load:

Product name	Article Number	Maximum Load (g)	Vent to Volume Ratio (in^{-1})
OmniTaper Surgical Tray	68015282	513.7	0.033
PrimeTaper Surgical Tray	68015321	513.7	0.033
PrimeTaper Surgical Tray GS Medium	68017268	563.5	0.033
OmniTaper Surgical Tray GS	68017203	563.5	0.033
Bone Reamer Tray	68015280	271.9	0.046
Prosthetic Tray	68015288	271.9	0.046

Comparison of Technological Characteristics

An overview of the similarities and differences between the proposed and predicate device is given in Table 2. The proposed Surgical and Prosthetic Trays and the predicate device Surgical Trays (K212281), have the same intended use, same sterilization method and parameters, are made of the same materials, undergo the same manufacturing process, have a similar design, and have identical instrument holder material, design and spacing between the holders. The use of the proposed Surgical and Prosthetic Trays has been validated through performance, biocompatibility and sterilization testing or via analysis of existing data for inclusion.

510(k) SUMMARY
Surgical and Prosthetic Trays, K220791

Table 2: Similarities and Differences between the proposed and predicate devices

<table>
<tr><th>Elements</th><th>Proposed Device
Surgical and Prosthetic Trays</th><th>Predicate Device
Surgical Trays (K212281)</th><th>Comparison</th></tr>
<tr><td>Manufacturer</td><td>Sirona Dental Systems GmbH</td><td>Sirona Dental Systems GmbH</td><td>Same Manufacturer</td></tr>
<tr><td>Indications for use</td><td>The Surgical and Prosthetic Trays are intended for organizing, sterilizing and storing of instruments.

The Surgical and Prosthetic 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 minute dry time.
<table>
<tr><th>Do not exceed the worst-case validated maximum load:Product name</th><th>Article Number</th><th>Maximum 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>
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<tr><td>Prosthetic Tray</td><td>68015288</td><td>271.9</td><td>0.046</td></tr>
</table></td><td>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.

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>Similar</td></tr>
<tr><td>Product code</td><td>KCT</td><td>KCT</td><td>Same</td></tr>
</table>

510(k) SUMMARY
Surgical and Prosthetic Trays, K220791

Elements	Proposed Device Surgical and Prosthetic Trays	Predicate Device Surgical Trays (K212281)	Comparison
General Design	Plastic trays with locking lid. Co-molded silicone and silicone grommet supports	Plastic tray with locking lid. Co-molded silicone and silicone grommet supports	Same
Dimensions	Medium Trays: 7.3 in x 5.5 in x 2.4 in Small Trays: 5.4 in x 3.9 in x 2.4 in	7.3 in x 5.5 in x 2.4 in	Same for the medium trays, different for the small trays
Material	Base – Radel 5000 Lid – Radel 5000 Overlay – Radel 5000 Tooling support - Silicone	Base – Radel 5000 Lid – Radel 5000 Overlay – Radel 5000 Tooling support - 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 GS: 563.5g PrimeTaper Surgical Tray GS Medium: 563.5g Prosthetic Tray: 271.9g Bone Reamer Tray: 271.9g	OmniTaper Surgical Tray: 513.7 g PrimeTaper Surgical Tray: 513.7 g	Different
Vent to volume ratio	OmniTaper Surgical Tray GS: 0.033 in^{-1} PrimeTaper Surgical Tray GS Medium: 0.033 in^{-1} Prosthetic Tray: 0.046 in^{-1} Bone Reamer Tray: 0.046 in^{-1}	OmniTaper Surgical Tray: 0.033 in^{-1} PrimeTaper Surgical Tray: 0.033 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 minute 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

510(k) SUMMARY
Surgical and Prosthetic Trays, K220791

Non-Clinical Performance Data

The proposed Surgical and Prosthetic Trays are reusable devices provided non-sterile which need to be end user sterilized. Sterilization of the proposed trays was validated according to the FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

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	Product tested	Purpose	Acceptance Criteria	Results
Sterilization cycle validation	• ANSI/AAMI/ISO 17665-1:2006/ (R)2013 • ISO 17665-2:2009	Proposed device	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	Proposed device	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
Cleaning (Manual Pre-Cleaning and automated Cleaning)	• AAMI TIR 30:2011 • ISO 15883-1:2014	Predicate device	To validate that the trays can be cleaned as specified on labeling	No visible soil. Protein and TOC content Limit <5 [µg/cm^2] <95 [µg/device]	Pass
Reprocessing of trays (cleaning and sterilization)	Internal Test Method	Predicate device	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	Predicate device	To confirm that the trays can withstand simulated use of up to 1,500 repeated reposition cycles	No significant wear of the holders	Pass
Packaging stesting	ISTA 2A(2011)	Predicate device	To confirm that the packaging protects the device during simulated distribution	No signs of cracks or ruptures on the surgical trays	Pass
Cytotoxicity	ISO 10993-5:2009	Predicate device	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

Conclusion

The conclusions drawn from the non-clinical test data and evaluation support that the proposed Surgical and Prosthetic Trays are as safe, as effective and perform as well as the legally marketed predicate device Dentsply Sirona Surgical Trays (K212281).