January 28, 2021

Implant Direct Sybron Manufacturing, LLC
Reina Choi
Regulatory Affairs Manager
3050 East Hillcrest Drive
Thousand Oaks, California 91362

Re: K202524
Trade/Device Name: Standard Sterilizable Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 21, 2020
Received: December 28, 2020

Dear Reina Choi:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202524

Device Name
Standard Sterilizable Tray

Indications for Use *(Describe)*

The Standard Sterilizable Tray is designed to hold various dental surgical and prosthetic instruments in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap (maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
(2) Gravity Steam – At 132°C for 15 minutes with a 30 minutes dry time.

- The tray is intended for sterilization of non-porous loads.
- Do not stack trays during sterilization.
- The tested Tray represents the worst case validated load of 667.52 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Standard Sterilizable Tray.

Model Name	**Model Number**	**Max # of Instruments**	**Max Load (g)**	**Vent to volume Ratio (in^{-1})**
Standard Surgical Kit	CSSK	46	667.52	0.021
Standard Surgical Kit Empty	SSK		385.2	0.021
InterActive™ Surgical Kit	CISK	34	662.70	0.021
InterActive™ Surgical Kit Empty	ISK		384.2	0.021

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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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

I. SUBMITTER

Implant Direct Sybron Manufacturing, LLC
3050 East Hillcrest Drive
Thousand Oaks, CA 91362

Contact Person: Reina Choi, Regulatory Affairs Manager
E-mail: reina.choi@implantdirect.com
Phone: (818) 307-3132

Date Prepared: January 27, 2021

II. DEVICE

Name of Device: Standard Sterilizable Tray
Common or Usual Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name: Sterilization Wrap (21 CFR 880.6850)
Regulatory Class: II
Product Code: KCT

III.PREDICATE DEVICE

Primary Predicate:
Mini Sterilizable Tray (K200858)

IV. DEVICE DESCRIPTION

The Standard Sterilizable Tray is a reusable perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage. The tray is designed to hold various dental surgical and prosthetic instruments in order to organize, steam sterilize, and transport the instruments between uses.

The Standard Sterilizable Tray is a container composed of three main components: a lid, a tray base and a variable inner tray, all made of polyphenylsulfone (Radel R5000). The inner tray has silicone rubber that is co-molded in the plastic of the inner tray as well as silicone grommets. In addition, accessory stainless-steel pan may be included in the tray.

The Standard Sterilizable Tray is available in one size with outer dimensions of 7.3 inch x 5.5 inch x 2.4 inch and offered in 2 inner tray configurations with varied instrument loads.

Model name	Model number	Max # of Instruments	Max load (g)	Vent to volume ratio (in^{-1})
Standard Surgical Kit	CSSK	46	667.52	0.021
InterActive™ Surgical Kit	CISK	34	662.70	0.021

The Standard Sterilizable Tray is available either empty or loaded with surgical and prosthetic instruments to support endosseous dental implants and abutments that are not subject devices to this submission. The empty tray, along with a complete load of instruments, weighs a maximum of 667.52 grams. The variable Inner Tray offers two configuration options to allow for the assembly of supporting surgical and prosthetic instruments.

V. INDICATIONS FOR USE

The Standard Sterilizable Tray is designed to hold various dental surgical and prosthetic instruments in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap (maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
(2) Gravity Steam – At 132°C for 15 minutes with a 30 minutes dry time.

- The tray is intended for sterilization of non-porous loads.
- Do not stack trays during sterilization.
- The tested Tray represents the worst case validated load of 667.52 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Standard Sterilizable Tray.

Model Name	Model Number	Max # of Instruments	Mass(g)	Vent to volume Ratio (in^{-1})
Standard Surgical Kit	CSSK	46	667.52	0.021
Standard Surgical Kit Empty	SSK		385.2	0.021
InterActive™ Surgical Kit	CISK	34	662.70	0.021
InterActive™ Surgical Kit Empty	ISK		384.2	0.021

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological characteristics		Subject Device (K202524) Standard Sterilizable Tray	Primary Predicate (K200858) Mini Sterilizable Tray	Comparison
Manufacturer		Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Same
Design Characteristic	General design	Plastic tray with locking lid co-molded silicone and silicone grommet supports and stainless steel component	Plastic tray with locking lid co-molded silicone and silicone grommet supports and stainless steel components	Same
	Dimensions	7.3 in x 5.5 in x 2.4 in	5.5 in x 4.0 in 2.25 in	Different
	Materials	Base – Radel 5000 Lid – Radel 5000 Inner tray – Radel 5000 Tooling support - Silicone Pan – Stainless steel	Base – Radel 5000 Lid – Radel 5000 Inner tray – Radel 5000 Tooling support – Silicone Pan – Stainless steel Bracket – Stainless steel	Same
	Air permeance	Yes	Yes	Same
	Maximum number of instruments	CSSK 46 CISK 34	CSSKM 21 CISKM 20 CDSKL 36 CDSKS 32 CPKM 14	Different
	Mass of maximum sterilization load	CSSK 667.52g CISK 662.70g	CSSKM 278.50 g CISKM 276.60 g CDSKL 354.10 g CDSKS 209.10 g CPKM 262.55 g	Different
	Vent to volume ratio	CSSK 0.021 in^{-1} CISK 0.021 in^{-1}	CSSKM 0.082 in^{-1} CISKM 0.082 in^{-1} CDSKL 0.087 in^{-1} CDSKS 0.087 in^{-1} CPKM 0.087 in^{-1}	Different

<table>
<tr><th colspan="2" rowspan="2">Technological characteristics</th><th>Subject Device
(K202524)</th><th>Primary Predicate
(K200858)</th><th rowspan="2">Comparison</th></tr>
<tr><th>Standard Sterilizable Tray</th><th>Mini Sterilizable Tray</th></tr>
<tr><td></td><td>Sterility</td><td>Non-sterile</td><td>Non-sterile</td><td>Same</td></tr>
<tr><td></td><td>Sterilization method</td><td>Moist heat gravity or pre vacuum</td><td>Moist heat gravity or pre vacuum</td><td>Same</td></tr>
<tr><td></td><td>Reusable</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td colspan="2">Intended use</td><td>Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage</td><td>Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage</td><td>Same</td></tr>
<tr><td colspan="2">Indication for Use</td><td>The Standard Sterilizable Tray is designed to hold various dental surgical and prosthetic instruments in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap (Maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
(2) Gravity Steam – At 132°C for 15 minutes with a 30 minutes dry time.

- The tray is intended for sterilization of non-porous loads.
- Do not stack trays during sterilization.
- The tested Tray represents the worst case validated load of 667.52 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Standard Sterilizable Tray.

<table><tr><th>Model Name</th><th>Model Number</th><th>Max # of</th><th>Mass (g)</th><th>Vent to volume</th></tr></table></td><td>The Mini Sterilizable Tray is designed to hold various dental surgical and prosthetic instruments in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap and sterilized in an FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
(2) Gravity Steam - At 132°C for 15 minutes with a 30 minutes dry time.

- The trays are intended for sterilization of non-porous loads.
- Do not stack trays during sterilization.
- The tested Tray represents the worst case validated load of 354.10 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Mini Sterilizable Tray.

<table><tr><th>Model Name</th><th>Model Number</th></tr></table></td><td>Similar</td></tr>
</table>

<table>
<tr><th rowspan="2">Technological characteristics</th><th colspan="5">Subject Device (K202524)</th><th colspan="2">Primary Predicate (K200858)</th><th rowspan="2">Comparison</th></tr>
<tr><th colspan="5">Standard Sterilizable Tray</th><th colspan="2">Mini Sterilizable Tray</th></tr>
<tr><td></td><td colspan="5"><table>
<tr><th></th><th></th><th>Instru-ments</th><th></th><th>Ratio (in^{-1})</th></tr>
<tr><td>Standard Surgical Kit</td><td>CSSK</td><td>46</td><td>667.52</td><td>0.021</td></tr>
<tr><td>Standard Surgical Kit Empty</td><td>SSK</td><td></td><td>385.2</td><td>0.021</td></tr>
<tr><td>InterActive™ Surgical Kit</td><td>CISK</td><td>34</td><td>662.70</td><td>0.021</td></tr>
<tr><td>InterActive™ Surgical Kit Empty</td><td>ISK</td><td></td><td>384.2</td><td>0.021</td></tr>
</table></td><td colspan="2"><table>
<tr><td>Standard Surgical Kit Mini</td><td>CSSKM</td></tr>
<tr><td>Standard Surgical Kit Mini Empty</td><td>SSKM</td></tr>
<tr><td>InterActive™ Surgical Kit Mini</td><td>CISKM</td></tr>
<tr><td>InterActive™ Surgical Kit Mini Empty</td><td>ISKM</td></tr>
<tr><td>Drill Stop Kit – Long</td><td>CDSKL</td></tr>
<tr><td>Drill Stop Kit – Long Empty</td><td>DSKL</td></tr>
<tr><td>Drill Stop Kit - Short</td><td>CDSKS</td></tr>
<tr><td>Drill Stop Kit – Short Empty</td><td>DSKS</td></tr>
<tr><td>Prosthetic Kit</td><td>CPKM</td></tr>
<tr><td>Prosthetic Kit Empty</td><td>PKM</td></tr>
<tr><td>Drill Stop Kit Bracket Set – Long</td><td>DSK – BKTL</td></tr>
<tr><td>Drill Stop Kit Bracket Set – Short</td><td>DSK - BKTS</td></tr>
<tr><td>Replacement Kit Pan</td><td>PAN</td></tr>
</table></td><td></td></tr>
</table>

Comparison Between Subject Device and Predicate

The Standard Sterilizable Tray is larger in size than the predicate and made of same materials as the predicate. The use of Standard Sterilizable Tray has been validated through biocompatibility and sterilization testing. Therefore, this does not raise new questions of substantial equivalence.

The vent to volume ratio for the Standard Sterilizable Tray is 0.021 in^{-1} while the predicate vent to volume ratio is 0.087 in^{-1}. While the Standard Sterilizable Tray has a lower vent to volume ratio, this has been demonstrated to not be an issue through sterilization validation testing.

The Standard Sterilizable Tray can hold more instruments and has a larger maximum sterilization load. The maximum sterilization load for the Standard Sterilizable Tray is 667.52g, while the predicate's maximum sterilization load is 354.10g. While the Standard Sterilizable Tray has a larger weight and more instruments, this has been demonstrated to not be an issue through sterilization testing and has been validated to assure a SAL of 10^{-6}.

The Standard Sterilizable Trays and predicate device have the same intended use. The indication for use is the same except for and various versions of inner tray for the predicate and the weight of the validated trays.

VII. SUMMARY OF NON-CLINICAL TESTING

Testing Methodology	**Purpose**	**Acceptance Criteria**	**Results**
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	The purpose of the testing is to observe the cytoxicity potential of the device extract.	Morphological Grade 2 (mild) or better	Pass
ISO 17664 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices	The purpose of this testing is to verify the continued performance of the device during its useful life.	No visual degradation, silicone retention performance	Pass

TIR30- A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices And TIR 12- Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	The purpose of this testing is to verify the effectiveness of the recommended cleaning process.	< 12 µg/cm2 of TOC will be recovered from devices cleaned using the recommended minimum cleaning processes. < 6.4 µg/cm2 of protein will be recovered from devices cleaned using the recommended minimum cleaning processes.	Pass
ISO 17665-1 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	The purpose of this testing is to verify the ability of the sterilization process to adequately sterilize the load.	6 log reduction at half-cycle	Pass
ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems	The purpose of this testing is to verify the durability of the device during transportation.	No damage	Pass

VIII. CONCLUSIONS

The conclusions drawn from the non-clinical test data demonstrates that the Standard Sterilizable Tray is as safe, as effective, and performs as well as or better than the legally marketed predicate, Mini Sterilizable Tray (K200858).