August 6, 2020

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

Re: K200858
Trade/Device Name: Mini Sterilizable Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 2, 2020
Received: July 6, 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,

Ramesh Kapil Panguluri, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200858

Device Name
Mini Sterilizable Tray

Indications for Use *(Describe)*
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:

Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
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 354.10 grams.
-Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Mini Sterilizable Tray.

Model Name	Model Number
Standard Surgical Kit Mini	CSSKM
Standard Surgical Kit Mini Empty	SSKM
InterActiveTM Surgical Kit Mini	CISKM
InterActiveTM Surgical Kit Mini Empty	ISKM
Drill Stop Kit - Long	CDSKL
Drill Stop Kit - Long Empty	DSKL
Drill Stop Kit - Short	CDSKS
Drill Stop Kit - Short Empty	DSKS
Prosthetic Kit	CPKM
Prosthetic Kit Empty	PKM
Drill Stop Kit Bracket Set - Long	DSK-BKTL
Drill Stop Kit Bracket Set - Short	DSK-BKTS
Replacement Kit Pan	PAN

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.

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) 444-3306

Date Prepared: August 3, 2020

II. DEVICE

Name of Device: Mini 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

Predicate (primary)
InterActive Complete Surgical Tray (K142519)

IV. DEVICE DESCRIPTION

The Mini 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 Mini Sterilizable Tray is a container composed of three main components: a lid, a cassette 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 components such as a pan and a bracket may be included in the tray.

The Mini Sterilizable Tray is available in one size with outer dimensions of 5.5 inch x 4.0 inch x 2.25 inch and offered in 5 inner tray configurations with varied instrument loads.

Model name	Model number	Max # of instruments	Max load mass(g)	Vent to volume ratio (in^{-1})
Standard Surgical	CSSKM	21	278.50	0.082

Kit Mini				
InterActive™ Surgical Kit Mini	CISKM	20	276.60	0.082
Drill Stop Kit - Long	CDSKL	36	354.10	0.087
Drill Stop Kit - Short	CDSKS	32	309.01	0.087
Prosthetic Kit	CPKM	14	262.55	0.082

The Mini 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 354.10 grams. The variable Inner Tray offers several configuration options to allow for the assembly of supporting surgical and prosthetic instruments.

V. INDICATIONS FOR USE

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:

Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
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 354.10 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Mini Sterilizable Tray.

Model Name	Model Number
Standard Surgical Kit Mini	CSSKM
Standard Surgical Kit Mini Empty	SSKM
InterActive™ Surgical Kit Mini	CISKM
InterActive™ Surgical Kit Mini Empty	ISKM
Drill Stop Kit - Long	CDSKL
Drill Stop Kit – Long Empty	DSKL
Drill Stop Kit - Short	CDSKS
Drill Stop Kit – Short Empty	DSKS
Prosthetic Kit	CPKM
Prosthetic Kit Empty	PKM
Drill Stop Kit Bracket Set - Long	DSK - BKTL
Drill Stop Kit Bracket Set - Short	DSK - BKTS
Replacement Kit Pan	PAN

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological characteristics		Subject Device Mini Sterilizable Tray	Predicate (primary) InterActive Complete Surgical Tray (K142519)	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 components	Plastic tray with locking lid and silicone retaining supports	Subject device uses co-molding for some silicone supports and includes a stainless steel pan and bracket
	Dimensions	5.5 in x 4.0 in x 2.25 in	7.2 in x 5.6 in 2.4 in	The subject device is smaller than the predicate
	Materials	Base – Radel 5000 Lid – Radel 5000 Inner tray – Radel 5000 Tooling support - Silicone Pan – Stainless steel Bracket – Stainless steel	Base – Radel 5100 Lid – Radel 5000 Inner tray – Radel 5100 Tooling support - Silicone	Base and Inner tray use Radel 5100 rather than Radel 5000. Both Radel plastics have similar mechanical properties. Predicate does not include stainless steel
	Air permeance	Yes	Yes	Same
	Maximum number of instruments	CSSKM: 21 CISKM: 20 CDSKL: 36 CDSKS: 32 CPKM: 14	45	Subject device has less instruments
	Mass of maximum sterilization load	CSSKM: 278.50 g CISKM: 276.60 g CDSKL: 354.10 g CDSKS: 209.01 g CPKM: 262.55 g	608.05 g	Subject device has a smaller maximum sterilization load mass

<table>
<tr><th colspan="2" rowspan="2">Technological characteristics</th><th>Subject Device</th><th>Predicate (primary)</th><th rowspan="2">Comparison</th></tr>
<tr><th>Mini Sterilizable Tray</th><th>InterActive Complete Surgical Tray (K142519)</th></tr>
<tr><td></td><td>Vent to volume ratio</td><td><table><tr><td>CSSKM</td><td>0.082 in^{-1}</td></tr><tr><td>CISKM</td><td>0.082 in^{-1}</td></tr><tr><td>CDSKL</td><td>0.087 in^{-1}</td></tr><tr><td>CDSKS</td><td>0.087 in^{-1}</td></tr><tr><td>CPKM</td><td>0.082 in^{-1}</td></tr></table></td><td>0.184 in^{-1}</td><td>Subject device has a lower vent to volume ratio</td></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 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:

Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
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</td><td>The InterActive Complete Surgical Tray is designed to hold various dental surgical drills and tools 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) Prevauum 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.
- The trays are recommended not to be stacked during sterilization.</td><td>The Mini Sterilizable tray is designed to hold instruments necessary to place prosthetics that the predicate is not.

Both devices are indicated to organize, steam sterilize, and transport instruments between uses.

Both devices require use of sterilizable wrap when autoclaving.

Both devices use the same sterilization cycles.</td></tr>
</table>

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<tr><th rowspan="2">Technological characteristics</th><th>Subject Device</th><th>Predicate (primary)</th><th rowspan="2">Comparison</th></tr>
<tr><th>Mini Sterilizable Tray</th><th>InterActive Complete Surgical Tray (K142519)</th></tr>
<tr>
<td></td>
<td>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>
<tr><td>Standard Surgical Kit Mini</td><td>CSSKM</td></tr>
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</table>
</td>
<td>- The Complete Surgical Tray represents the worst case validated load due to the number of components (45 instruments) and the weight of 608.05 grams.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Interactive Complete Surgical Tray.
- The tray will be marketed in following variations.
<table>
<tr><th>Device Model Name</th><th>Max no. of Instruments</th><th>Weight of each tray with instruments (gms.)</th></tr>
<tr><td>CST</td><td>45</td><td>608.05</td></tr>
<tr><td>ICST</td><td>34</td><td>467.26</td></tr>
<tr><td>IBST</td><td>18</td><td>453.59</td></tr>
<tr><td>IST</td><td>0</td><td>404.37</td></tr>
</table>
</td>
<td>The Mini Sterilizable tray has a maximum validated load of 354.10 g while the predicate has a maximum of 608.05</td>
</tr>
</table>

Analysis of Differences Between Subject Device and Predicate

In addition to silicone supports, the Mini Sterilizable Tray uses co-molding to integrate the silicone used to hold tooling. The co-molding replaces the silicone o-rings used in the predicate. The use of co-molded silicone supports was validated though simulated use and wear testing.

In addition to the surgical tooling necessary to place a dental implant, the Mini Sterilizable Tray is designed to hold prosthetic tooling necessary to place a restoration. Prosthetic instruments are made of the same materials and are used during dental procedures like the surgical tooling. Therefore, this does not raise new questions of substantial equivalence.

The Mini Sterilizable Tray includes a stainless steel pan and bracket that are not included in the predicate device. The pan is used to hold drills and other tooling post-surgical use. The bracket aids in the placement of drill stops on the surgical drills. The use of these components has been validated through the use of biocompatibility and sterilization testing.

The Mini Sterilizable Tray uses Radel 5000 for all plastic components where the predicate device uses it only for the tray lid. Since the predicate uses the same plastic for the tray lid this does not pose a new question of substantial equivalence.

The vent to volume ratio for the Mini Sterilizable Tray is $0.087in^{-1}$ while the predicate vent to volume ratio is $0.184\ in^{-1}$. While the Mini Sterilizable Tray has a lower vent to volume ratio, this has been demonstrated to not be an issue through sterilization validation testing.

The Mini Sterilizable Tray is smaller and has a smaller maximum sterilization load. The maximum sterilization load for the Mini Sterilizable Tray is 354.10 g while the predicate maximum sterilization load is 608.05 g. The lower weight does not represent a new worst-case but has been validated to assure an SAL of 10^{-6}.

The Mini Sterilizable Trays and predicate device have the same intended use. The indication for use is the same except for the ability to hold prosthetic tooling and the weight of the validated trays.

Summary:
The design differences between the subject and predicate device was evaluated through performance, biocompatibility, and sterilization testing. The documentation submitted in the premarket notification demonstrates that the Mini Sterilizable Tray is substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:

Biocompatibility
The Mini Sterilizable Trays were successfully tested for biocompatibility testing in accordance with ISO 10993-1 and ISO 10993-5. The results of a cytotoxicity tests demonstrated that extracts of the device did not elicit a cytotoxic response in the test system. The results of the testing were used to address questions related to substantial equivalence based on differences in manufacturing processes (addition of DLC coating) between the subject and predicate device (K142519).

Performance testing
Non-clinical performance and wear testing of the Mini Sterilizable Tray through simulated use testing. The Sterilizable Mini Tray and its co-packaged components were subjected to 120 simulated uses cycles. Simulated use testing demonstrated that the co-packaged components worked as designed after the simulated use. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject and predicate device (K142519).

Cleaning Validation
Cleaning efficiency was successfully conducted in accordance with AAMI TIR30 and AAMI TIR12. The study used a clinically-relevant, simulated soil, extended drying time between soiling and processing, and minimal processing parameters for the cleaning process. Extracts of proposed devices were analyzed for total organic carbon (TOC) and protein as residual soil markers. The results of the testing were used to address questions related to substantial equivalence based on differences in product use between the subject and predicate device (K142519).

Sterilization
Sterilization validation was successfully conducted in accordance with ISO 17665-1. The overkill approach as per ISO 17665-1 was used to demonstrate an SAL of 10^{-6}. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and predicate device (K142519).

Transportation Simulation Testing
Transportation simulation testing validates the packaging and distribution of the Mini Sterilizable Tray and co-packaged instruments. The tests performed included Handling, Stacking, Loose-Load Vibration, Vehicle Vibration, Concentrated Impact, and an additional Handling test per ASTM D4169-16 DC-13, Assurance Level I, Schedules: A, C, F, E, J, A. The transportation testing demonstrates that the Mini Sterilizable Trays and co-packed components were not damaged and remained in their designated location. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject and predicate device (K142519).

VIII. CONCLUSIONS

The Mini Sterilizable Tray was evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data included in this submission, the Mini Sterilizable Tray has been shown to be as safe, as effective and perform as well or better than the legally marketed predicate device, the InterActive Complete Surgical Tray (K142519).