DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 15, 2015

Implant Direct Sybron Manufacturing LLC
Debleena Sinha, M.S.
Regulatory Affairs Specialist
3050 East Hillcrest Drive
Thousand Oaks, CA 91362

Re: K142519
Trade/Device Name: InterActive Complete Surgical Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: March 20, 2015
Received: March 23, 2015

Dear Ms. Sinha:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)*

K142519

Device Name

InterActive Complete Surgical Tray

Indications for Use *(Describe)*

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) Prevaccum Steam – At 132^{0}C for 4 minutes with a 20 minutes dry time.
(2) Gravity Steam - At 132^{0}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.
- 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.

Device Model Name	Max no. of Instruments	Weight of each tray with instruments (gms.)
CST	45	608.05
ICST	34	467.26
IBST	18	453.59
IST	0	404.37

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.

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510 (K) Summary (21CFR 807.92(a)(1))

1. Submitter Information

510 K Sponsor	Implant Direct Sybron Manufacturing LLC
Address	3050 East Hillcrest Drive Thousand Oaks, CA 91362
Registration Number	3001617766
Correspondence Contact	Debleena Sinha, M.S Specialist, Regulatory Affairs Ph: 818-444-3306 Fax: 818-444-3406 Email: debleena.sinha@implantdirect.com
Date Summary Prepared	April 6, 2015

2. Device Name and Classification

Trade Name	InterActive Complete Surgical Tray
Classification Name	Sterilization Wrap Containers, Trays, Cassettes, and other Accessories
Common Name	Instrument Sterilization Tray
Regulation Number	21 CFR 880.6850
Product Code	KCT
Regulatory Class	II

3. Predicate Devices

Conmed Linvatech Instrument Sterilization Tray (K052992)

Polyvac Inc. Surgical Instrument Delivery Tray (K012105)

Tuttnauer USA Co Ltd. Cassette Container (K990761)

C/T Medical Systems Sterilization Cassettes (K980065)

4. Description of Device

The **InterActive Complete Surgical Tray** is a reusable rigid sterilization container or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit which contains and protects the interior components during sterilization. Each tray consists of three components - a base tray, a lid, and an internal individualized insert tray. All of the three components are perforated for steam penetration. The internal insert tray has the ability to hold individualized pieces and accessories which include dental tools, drills, and ratchet. The tray is available in only one size of approximately 7.2 inches X 5.6 inches X 2.4 inches and will be marketed in four different variations – (1) InterActive Complete Surgical Tray (ICST) containing 34 instruments, (2) InterActive Basic Surgical Tray (IBST) containing almost half the number of instruments as ICST, (3) InterActive

Surgical Tray (IST), empty tray containing no instruments, and (4) Complete Surgical Tray (CST), containing 45 instruments.

The rigid multi-piece tray holds dental device apparatus and accessories before, during, and after the sterilization process. The tray set has a locking lid to contain the products. The trays are designed to fit any standard autoclave, which allows it to be effective for sterilization and be able to withstand the environment of repeated steam sterilization cycles in normal operating room. Since the trays are perforated, an FDA cleared sterilization wrap must be used for sterilization purposes to maintain the sterility of the contents.

The trays are reusable and the tray material allows repeated sterilization cycles. The lid, base, and insert are made of Radel R-5000. This material is a polymer resin produced by Solvay Advanced Polymers, LLC, and is identical to the Radel used in predicate device cleared under K052992 and K012105. Radel R 5000 CL 301 is used for the lid, and Radel R 5100 NT15 is used for base and insert tray where all the drills and tools are mounted. The small circular brackets (grommets) throughout the insert tray which are used to contain the drills and the tool holder with cradle on the base tray are made of medical grade silicone material which has been manufactured to meet FDA CFR 177.2600. These brackets and holders are used to secure the

instruments during transport, sterilization, and storage. Although these trays are reusable they will not be serviced or repaired.

The instruments to be sterilized in the proposed tray are all non-porous devices and include dental surgical drills and tools. The tools are class I exempt and the drills have Class II pre-market notification clearance.

5. Intended Use

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) Prevaccum Steam – At 132^{0}C for 4 minutes with a 20 minutes dry time.

(2) Gravity Steam - At 132^{0}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.
- 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.

Device Model Name	Max no. of Instruments	Weight of each tray with instruments (gms.)
CST	45	608.05
ICST	34	467.26
IBST	18	453.59
IST	0	404.37

6. Substantial Equivalence

The tables below shows that the **InterActive Complete Surgical Tray** compared against 510(K) cleared products. The comparison analysis consists of the products' intended use, technological characteristics and performance testing to support the substantial equivalency to their corresponding predicate devices.

TABLE1: Substantial Equivalence: Comparison of Proposed Device with Predicates on Technological Considerations

Manufacturer	**Implant Direct**	**ConMed Linvatech**	**PolyVac Inc.**	**Tuttnauer USA Co Ltd**	**C/TMedical Systems**
	Proposed Device	Predicate	Predicate	Predicate	Predicate
510 (K)	K142519	K052992	K012105	K990761	K980065
Trade Name	InterActive Complete Surgical Tray	Instrument Sterilization Tray	Surgical Instrument Delivery System	Mini Container Cassette; Standard Cassette Container	Sterilization cassettes
Product Code	KCT	FRG	KCT	FRG	KCT
Intended Use	Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage	Perforated trays with lids to hold surgical instruments in place during transport, steam sterilization, and storage	Perforated trays with lids to hold surgical instruments in place during transport, steam sterilization, and storage	Dental instrument cassette system to hold instruments in place during transport, steam sterilization, and storage	Dental instrument cassette system to hold instruments in place during transport, steam sterilization, and storage
Material Composition	Polymer Resin Radel-5000, biomedical grade silicone	Polymer Resin Radel-5000, biomedical grade silicone	Radel-5000 plastic, Biomedical grade silicone, and Aluminum, 300 series stainless steel	Plastic Polymer, biomedical grade silicone	Plastic, Metal, and Stainless Steel container

Manufacturer	Implant Direct	ConMed Linvatech	PolyVac Inc.	Tuttnauer USA Co Ltd	C/TMedical Systems
Design	Plastic tray with locking lid and silicone containment brackets	Plastic tray with stainless steel latch and silicone containment brackets	Tray made of plastic or metal base with lid	Small to medium tray with silicone mat inserts	Trays and cassettes made of metal and plastic. Latch made of stainless steel.
Sterilization by **(1) Gravity Steam** (2) **Pre Vaccum Steam**	 Yes Yes	 Yes Yes	 Yes Yes	 Yes Yes	 Yes Yes
Air Permeance	Yes	Yes	Yes	Yes	Assume
Locking system to hold lid in place	Yes	Yes	Yes	Yes	Yes
Reusable	Yes	Yes	Yes	Yes	Yes
Material compatibility with sterilization process	Yes	Yes	Yes	Yes	Yes

7. Non-Clinical Performance Testing

The performance testing of the proposed device complies with a special control: *21 CFR 880.6850 - Class II Special Controls Guidance Document for sterilization wrap (pack, sterilization wrapper, bag, and accessories*. The performance characteristics of the device are supported by Steam Sterilization validations, Cytotoxicity tests,

Cleaning validations, and Distribution studies conducted on the **Complete Surgical Tray** taking worst case scenarios into account.

TABLE 2: Substantial Equivalence: Comparison with Predicates on Performance Testing

Manufacturer	**Implant Direct**	**ConMed Linvatech**	**PolyVac Inc.**	**Tuttnauer USA Co Ltd**	**C/T Medical Systems**
	Proposed Device	Predicate	Predicate	Predicate	Predicate

Manufacturer	Implant Direct	ConMed Linvatech	PolyVac Inc.	Tuttnauer USA Co Ltd	C/T Medical Systems
510 (K)	K142519	K052992	K012105	K990761	K980065
Sterilant Penetration Studies	Yes Steam Sterilization Validations conducted as per AAMI/ANSI/ISO 17665; AAMI TIR 12	Yes	Yes	Yes	Yes
Toxicological Properties (biocompatibilty)	Yes Cytotoxicity Tests conducted as per ISO 10993 - 5; ISO 10993 -12	Yes Brackets and containment mats made from Biomedical grade silicone	Yes Biocomapatibilty tested to USP requirements	Yes Cassette inserts made from biomedical grade silicone	Not stated in summary
Transportation studies (Packaging Integrity)	Yes Distribution Studies conducted as per ASTM D4169	Not stated in summary	Not stated in summary	Not stated in summary	Not stated in summary
Cleaning Instructions for Reusable devices	Yes Cleaning Validations conducted as per AAMI TIR 30; AAMI TIR 12	Not stated in summary	Not stated in summary	Not stated in summary	Yes
Material Compatibility (repeat sterilization)	Yes Radel Technical Data Sheet	Yes Radel	Yes Radel	Not stated in summary	Not stated in summary

Manufacturer	Implant Direct	ConMed Linvatech	PolyVac Inc.	Tuttnauer USA Co Ltd	C/T Medical Systems
Drying Time	Yes Validated in Steam Sterilization report AAMI/ANSI/ISO 17665; AAMI TIR 12	Not stated in summary	Not stated in summary	Not stated in summary	Yes Drying time in labeling
Vent/Volume Ratio	All proposed trays are 0.184 in^2/in^3	Not stated in summary	0.02276 in^2/in^3	Not stated in summary	Not stated in summary

The proposed devices have high vent to volume ratio, allowing easier sterilant penetration than the predicate device.

The Complete Surgical Tray (CST) container represents the worst case vent to volume ratio for the Surgical Tray System making this container the most challenging container to achieve sterilization.

8. Clinical Testing

No clinical tests were conducted.

9. Summary and Conclusion

A comparison of the intended use, technological characteristics, and performance studies conducted on the InterActive Complete Surgical Tray demonstrate that the device is substantially equivalent to its predicate devices K052992 (ConMed Linvatech Instrument Sterilization Tray), K012105 (Polyvac Surgical Instrument Delivery System), K990761 (Tuttnauer USA Co Ltd. Cassette Container), and K980065 (C/T Medical Systems Sterilization Cassettes).