March 6, 2020

AVINENT Implant System, S.L.U.
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K191566
Trade/Device Name: Avinent Surgical Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 28, 2020
Received: February 4, 2020

Dear Angela Blackwell:

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 Sreekanth Gutala, 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)*

K191566

Device Name
Avinent Surgical Tray

Indications for Use *(Describe)*

The Avinent 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 the following cycle:
Prevaccum Steam - At 132° for 4 minutes with a 30 minute dry time.
-The trays are intended for sterilization of non-porous loads.
-The trays are recommended not to be stacked during sterilization.
-The Biomimetic Coral Sterilization Cassette Guided Surgery represents the worst case validated load due to the number of components (32 instruments) and the weight of 599.6 grams.
-Avinent Implant System SLU does not make any lumen claims for the Avinent Surgical Tray.
-The tray will be marketed in the variations found in the following table.

DEVICE MODEL NAME	MAX no. of INSTRUMENTS	WEIGHT of each tray FULL (g)	WEIGHT of each tray EMPTY (g)
Biomimetic Coral Sterilization Cassette Guided Surgery	32	599.6	510.0
Biomimetic Ocean Sterilization Cassette Guided Surgery	26	592.8	510.0

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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Avinent Surgical Tray 510k Summary K191566

AVINENT Implant System S.L.U.

Pol. Ind. Santa Anna I - 08251 Santpedor Barcelona, Spain

+34 902 38 38 48

March 3, 2020

Submission Contact: Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704) 450-9934
angela@blackwelldevice.com

Classification Name: Sterilization Wrap Containers, Trays, Cassettes, and other accessories

Common Name: Instrument Sterilization Tray

Regulation Number: 21 CFR 880.6850

Product Code: KCT

Class: II

Predicate Device: Implant Direct Interactive Complete Surgical Tray K142519

Device Description:

The Avinent 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 tray has the ability to hold individualized pieces and accessories which include dental tools, drills, and torque wrench. The tray is available in one size, 207.5 x 157.5 x 71.7mm. The tray comes in two variations, Coral and Ocean.

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 them 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 wrap must be used for sterilization purposes to maintain the sterility of 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 K142519. Radel R 5000 CL 301 is used for the lid, Radel R-5100 BK # 937 is used for the base and Radel R-5100 GY #1037 is used for the insert tray where all the drills and tools are mounted. The small circular brackets (grommets) throughout the insert tray which are used to contain 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 21 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 trays are all non-porous devices and included dental surgical drills and tools. The tools and drills are all class I exempt.

Indications for Use:

The Avinent 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 the following cycle:

Prevaccum Steam - At 132° for 4 minutes with a 30 minute dry time.

-The trays are intended for sterilization of non-porous loads.

-The trays are recommended not to be stacked during sterilization.

-The Biomimetic Coral Sterilization Cassette Guided Surgery represents the worst case validated load due to the number of components (32 instruments) and the weight of 599.6 grams.

-Avinent Implant System SLU does not make any lumen claims for the Avinent Surgical Tray.

-The tray will be marketed in the variations found in the following table.

DEVICE MODEL NAME	**MAX no. of INSTRUMENTS**	**WEIGHT of each tray FULL (g)**	**WEIGHT of each tray EMPTY (g)**
Biomimetic Coral Sterilization Cassette Guided Surgery	32	599.6	510.0
Biomimetic Ocean Sterilization Cassette Guided Surgery	26	592.8	510.0

Technological Characteristics Comparison Table:

The table below provide a technological characteristics comparison of the Avinent Surgical Tray to the predicate device the InterActive Complete Surgical Tray.

Device	Avinent Surgical Tray (K191566)	InterActive Complete Surgical Tray (K142519)
Product Code	KCT	KCT

Indications for Use	The Avinent 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 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.
Material Composition	Polymer Resin Radel-5000, biomedical grade silicone	Polymer Resin Radel-5000, biomedical grade silicone
Design	Plastic tray with locking lid and silicone containment brackets.	Plastic tray with locking lid and silicone containment brackets.
Sterilization by 1 Gravity Steam 2 Pre Vaccuum Steam	 No Yes	 Yes Yes
Air Permeance	Yes	Yes
Vent to Volume Ratio	0.011 in^2/in^3	.184 in^2/in^3
Locking System to hold lid in place	Yes	Yes
Reusable	Yes	Yes
Stackable	No	No
Material compatibility with sterilization process	Yes	Yes
Sterilant Penetration Studies	Yes	Yes
Biocompatibility	Cytotoxicity tests conducted according to ISO 10993-5 and –12.	Cytotoxicity tests conducted according to ISO 10993-5 and –12.
Cleaning Instructions for Reusable Devices Validated	Yes	Yes
Repeat Sterilization to show material compatibility over time	Yes	Yes
Drying Time	Yes	Yes
Method to Preserve Sterility of the Tray	FDA cleared wrap	FDA cleared wrap

Summary of Non-Clinical Testing:

Provided below are the non-clinical testing performed with the subject device to demonstrate that the device met the acceptance criteria of the test method or the standard.

Name of Testing	Purpose of Testing	Acceptance Criteria	Results
Cleaning Validation	Validate the cleaning cycle in the instructions for use	No visible soil. Hemogloblin less than 2.2µg/cm^2. Protein level ≤6.4 2µg/cm^2. MEM reactivity grade of 2 or less.	No visible soil. All acceptance criteria met.

Steam Sterilization Validation	Validate the half-cycle of the cycle in the instructions for use	No growth on half cycles. No moisture on full drying cycle. Pass on Chemical Indicators half and full cycle.	Pass on chemical indicators half and full cycle. No moisture on full drying cycle. No growth on half cycle.
100 cycles sterilization	Show the tray will last at least 100 sterilization cycles	Pass visual inspection and test of functionality.	At all cycle counts passed visual inspection and test of functionality.
Cytotoxicity	Sterilized instruments were tested to demonstrate their were no residuals on them which would change their biocompatibility.	Pass is a score of no greater than 2	Pass with score of 0

Cleaning validation using a manual method was done following simulated use according to the cleaning method in the instructions for use. Steam sterilization validation (half cycle) based on the cycle listed in the indications for use was completed. A second steam sterilization validation based on this cycle was done with thermal profiling. Sterilization of the tray was done to verify the tray safely last for 100 cycles. No changes were noted in the test articles after 100 cycles. Cytotoxicity (ISO 10993-5) of the instruments placed in the tray for sterilization was done after a sterilization cycle was completed to show there were no residuals from the tray on the instruments which would change their biocompatibility.

Conclusion: The conclusions drawn from the nonclinical test demonstrate that the Avinent Surgical Tray is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Interactive Complete Surgical Tray.