March 1, 2021

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

Re: K201533
Trade/Device Name: Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 01, 2021
Received: February 05, 2021

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,

Clarence W. Murray III, 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)*
K201533

Device Name
Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes

Indications for Use *(Describe)*
Avinent Sterilization Cassettes are 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 Sterilization Cassettes.
-The tray will be marketed in the following variations.

Device Model Name	Max No. of Instruments	Weight of tray full (g)	Weight of tray empty (9g)
Biomimetic Coral Sterilization Cassette	30	593.4	510.0
Biomimetic Ocean-Iceberg Sterilization Cassette	26	567.8	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.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes

AVINENT Implant System S.L.U.

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

+34 902 38 38 48

510k Summary – K201533

February 25, 2021

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

Device Trade Name: Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes

Regulation Number: 21 CFR 880.6850

Product Code: KCT

Class: II

Predicate Device: Avinent Surgical Tray K191566 Coral and Ocean Guided Surgery Sterilization Cassettes

Device Description:

The Avinent Sterilization Cassettes are 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 trays in this submission are Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes.

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 K191566. 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:

Avinent Sterilization Cassettes are 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 Sterilization Cassettes.
-The tray will be marketed in the following variations.

DEVICE MODEL NAME	**MAX no. of INSTRUMENTS**	**WEIGHT of each tray FULL (g)**	**WEIGHT of each tray EMPTY (g)**
Biomimetic Coral Sterilization Cassette	30	593.4	510.0
Biomimetic Ocean-Iceberg Sterilization Cassette	26	567.8	510.0

Comparison of Technological Characteristics:

The table below shows that the Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes compared to the predicate device the Avinent Surgical Tray (Coral and Ocean Guided Surgery Variations).

Device	Subject Device: Avinent Biomimetic Coral and Ocean-Iceberg Sterilization Cassettes (K201533)	Predicate Device: Avinent Surgical Tray Coral and Ocean Guided Surgery Sterilization Cassettes (K191566)	Comparison
Product Code	KCT	KCT	Same
Indications for Use	Avinent Sterilization Cassettes are 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 Sterilization Cassettes.	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.	Same other than the name of the device.
Material Composition	Polymer Resin Radel-5000, biomedical grade silicone	Polymer Resin Radel-5000, biomedical grade silicone	Same

Design	Plastic tray with locking lid and silicone containment brackets.	Plastic tray with locking lid and silicone containment brackets.	Same
Dimensions	207.5 x 157.5 x 71.7mm	207.5 x 157.5 x 71.7mm	Same
Sterilization by 1 Gravity Steam 2 Pre Vaccuum Steam	 No Yes	 No Yes	Same
Air Permeance	Yes	Yes	Same
Vent to Volume Ratio	0.011 in^2/in^3	0.011 in^2/in^3	Same
Locking System to hold lid in place	Yes	Yes	Same
Reusable	Yes	Yes	Same
Stackable	No	No	Same
Material compatibility with sterilization process	Yes	Yes	Same
Sterilant Penetration Studies	Yes	Yes	Same
Biocompatibility	Provided by material suppliers. Cytotoxicity tests conducted according to ISO 10993-5 and –12.	Provided by material suppliers. Cytotoxicity tests conducted according to ISO 10993-5 and –12.	Same
Cleaning Instructions for Reusable Devices Validated	Yes	Yes	Same
Repeat Sterilization to show material compatibility over time	Yes	Yes	Same
Drying Time	Yes	Yes	Same
Method to Preserve Sterility of the Tray	FDA cleared wrap	FDA cleared wrap	Same
Reference Numbers referring to tray contents	Coral 0376 Ocean-Iceberg 2725	Coral G.S. 3003 Ocean G.S. 3005	Different because two reference numbers were cleared in K191566 and two additional ones are the subject of this 510k (K201533)

Summary of Non-Clinical Testing:

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. <6.4 µg/cm^2 protein and < 2.2 µg/cm^2 hemoglobin on device after cleaning PASS
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.	10^{-6} SAL 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 No evidence of lysis – Non-Cytotoxic

Cleaning validation using a manual method was done following simulated use according to the cleaning method in the instructions for use. Six simulated use cycles consisting of contamination, cleaning, and sterilization were performed prior to validation. Four articles were used. The MEM article, negative article and negative device control were not simulated use articles. The positive was treated as a test article during the simulated use cycles. The test soil was defibrinated blood soil. The residuals tested were hemoglobin, protein, and minimal essential media.

Steam sterilization validation (half cycle) based on the cycle listed in the indications for use was completed. Each test article was evaluated to a sterility assurance level of ≤10^{-6} using the biological indicator overkill method. Dry times were validated using full cycle parameters. A second steam sterilization validation based on this cycle was done full cycle 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. A visual inspection, photographs, and a test of functionality were done every 10 cycles. Test articles were rewrapped after every 10 cycles.

Biocompatibility information was provided on all the materials used in the cassettes. 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 non-clinical tests demonstrate the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.