February 19, 2025

Implant Microdent System S.L.U.
Joan Muñoz
COO and R&D Director
C/Carles Buïgues, 1 1 Pol. Ind. Can Magre
Santa Eulalia de Ronçana, Barcelona 08187
Spain

Re: K242023
Trade/Device Name: Microdent Sterilization Cassette
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 23, 2025
Received: January 23, 2025

Dear Joan Muñoz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.02.19 13:34:26 -05'00'

for: Christopher K. Dugard
Division Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242023

Device Name
Microdent Sterilization Cassette

Indications for Use *(Describe)*
Microdent Sterilization Cassette is intended to organize, protect, and store various dental surgical drills and tools in order to organize and facilitate the sterilization process by allowing steam penetration and air removal.
When used in conjunction with FDA-cleared sterilization accessories (wrap, biological indicators, and chemical indicators) in an FDA-cleared sterilizer, sterility of the enclosed medical devices is maintained until used.
The sterilization cassette is intended for sterilization in a pre-vacuum steam sterilizer utilizing this recommended cycle:
- Temperature: 270°F/132°C
- Exposure time: 4 minutes.
- Drying time: 20 minutes.
- The cassettes are not to be stacked during sterilization.
- KTF and KBE references represent the worst case/best case validated load due to the total weight of 509 grams and 220 grams respectively.
- Implant Microdent System S.L. does not make any lumen claims for the Microdent Sterilization Cassette.

The following list of sterilization cassette models are available and the corresponding instrument load weight that can be sterilized in each model is as listed.

REFERENCE	WEIGHT	DIMENSIONS	VOLUME TO VENT RATIO
KCIGN	481g	190x140x6.5mm	3.38 mm (0.133 inch)
KCIEK	481g	190x140x6.5mm	3.38 mm (0.133 inch)
KIO	450g	200x105x34mm	27.737 mm (1.092 inch)
KFM	450g	190x140x61.5mm	3.38 mm (0.133 inch)
KTF	509g	184x136x31mm	131.98 mm (5.196 inch)
KEO	464g	190x140x61.5mm	3.38 mm (0.133 inch)
KBE	220g	143x79x23mm	24.36 mm (0.959 inch)
KCF	262g	143x99.5x61mm	3.302 mm (0.130 inch)

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.

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510(k) Summary

K242023

DATE PREPARED: 2025-02-10

SUBMITTER NAME: Implant Microdent Systems S.L.U.
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DEVICE TRADE NAME: Microdent Sterilization Cassette

COMMON NAME: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
REGULATION DESCRIPTION: Sterilization wrap
REGULATION NUMBER: 21 CFR 880.6850
PRODUCT CODE: KCT

PREDICATE DEVICE(S): PolyVac Inc (PolyVac Surgical Instrument Delivery System) (K012105)

DEVICE DESCRIPTION:

Microdent Sterilization Cassette consists of different sizes of the same basic configuration (maximum weight 509 gr). All systems consist of a minimum of a plastic base and cover. Each cover can be fastened to its corresponding base by means of locking tab or guides. Accessories may be used with systems to organize or separate contents to be placed in them for use.

The Delivery Systems are designed using plastic and metal materials that can be reused with steam sterilization methods. Each tray and cover have an evenly distributed hole pattern in relation to its size.

MICRODENT
IMPLANT SYSTEM

INDICATIONS FOR USE:

Microdent Sterilization Cassette is intended to organize, protect, and store various dental surgical drills and tools in order to organize and facilitate the sterilization process by allowing steam penetration and air removal.

When used in conjunction with FDA-cleared sterilization accessories (wrap, biological indicators, and chemical indicators) in an FDA-cleared sterilizer, sterility of the enclosed medical devices is maintained until used.

The sterilization cassette is intended for sterilization in a pre-vacuum steam sterilizer utilizing this recommended cycle:

- Temperature: 270°F/132°C

- Exposure time: 4 minutes.

- Drying time: 20 minutes.

- The cassettes are not to be stacked during sterilization.

- KTF and KBE references represent the worst case/best case validated load due to the total weight of 509 grams and 220 grams respectively.

- Implant Microdent System S.L. does not make any lumen claims for the Microdent Sterilization Cassette.

The following list of sterilization cassette models are available and the corresponding instrument load weight that can be sterilized in each model is as listed.

REFERENCE	WEIGHT	DIMENSIONS	VOLUME TO VENT RATIO
KCIGN	481g	190x140x6.5mm	3.38 mm (0.133 inch)
KCIEK	481g	190x140x6.5mm	3.38 mm (0.133 inch)
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KCF	262g	143x99.5x61mm	3,302 mm (0.130 inch)

MICRODENT
IMPLANT SYSTEM

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of a technology comparison, Microdent Sterilization Cassettes are compared with the following previously cleared devices:

Summary of comparison with predicate devices	**Proposed Device (K242023)**	**Predicate Device (K012015)**	**Comments**
	Microdent Sterilization Cassette	PolyVac Surgical Instrument Delivery System	
Appearance	 (KBE)	 (Minitainer II)	Similar
Classification / PROCODE	880.6850 (KCT)	880.6850 (KCT)	Same
Intended Use	Microdent Sterilization Cassette is intended to organize, protect, and store various dental surgical drills and tools in order to organize and facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with FDA-cleared sterilization accessories (wrap, biological indicators, and chemical indicators) in an FDA-cleared sterilizer, sterility of the enclosed medical devices is maintained until used. The sterilization cassette is intended for sterilization in a pre-vacuum steam sterilizer utilizing this recommended cycle: Temperature: 270°F/132°C Exposure time: 4 minutes. Drying time: 20 minutes. The cassettes are not to be stacked during sterilization. KTF and KBE references represent the worst case/best case validated load due to the total weight of 509 grams and 220 grams respectively. Implant Microdent System S.L. does not make any lumen claims for the Microdent Sterilization Cassette.	PolyVac's delivery systems are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used. PolyVac's delivery systems are to be sterilized in one of the following cycles: Prevacuum Steam: 132°C - 4 minutes minimum Dry for 20 - 40 minutes as needed Gravity Steam: 132°C - 30 minutes minimum Gravity Steam: 121°C - 55 minutes minimum _ Dry for 20 - 50 minutes as needed	Similar; the subject device does not have a gravity steam sterilization cycle claim.

Summary of comparison with predicate devices	Proposed Device (K242023)	Predicate Device (K012105)	Comments
	Microdent Sterilization Cassette	PolyVac Surgical Instrument Delivery System	
Description	- Base, modular insert trays and covers - Evenly distributed perforated hole pattern. -Silicone mats	- Base, modular insert trays and lids - Evenly distributed perforated hole pattern. - Silicone mats	Similar
Dimensions (l x w x h)	Largest: 184 x 136 x 31 mm Smallest: 43 x 79 x 23 mm.	17.3 x 7.25 x 4 mm	Different
Maximum weight	509 kg	Not stated in summary	N/A
Sterilant Penetration (air permeance / perforations)	Evenly distributed hole pattern	Evenly distributed hole pattern	Same
Microbial Barrier Properties	To be used in conjunction with an FDA cleared sterilization wrap.	To be used in conjunction with an FDA cleared sterilization wrap.	Same
Shelf Life	Reusable	Reusable	Same
Steam Sterilization Parameters	- Temperature: 270°F/132°C - Exposure time: 4 minutes. - Drying time: 20 minutes.	Prevacuum Steam: 132ºC – 4 minutes minimum. Dry for 20-40 minutes as needed Gravity Steam: 132°C - 30 minutes minimum Gravity Steam: 121°C - 55 minutes minimum _ Dry for 20 - 50 minutes as needed	Similar

Microdent Sterilization Cassettes are similar in fundamental scientific technology to the predicate devices in that they all have been designed, manufactured, and tested in compliance with FDA'S Class II device (product code KCT).

Microdent Sterilization Cassettes are technologically similar in materials, intended use, packaging, labeling and performance to the predicate devices currently marketed in the U.S. The only differences the subject devices and the predicates are in design and dimensions.

MICRODENT
IMPLANT SYSTEM

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use.

Non-clinical testing listed in the table below and performed in foreseeable operating conditions showed correct operation of the device as per its intended use.

Summary of Non-Clinical Testing				
Test Name	**Test Methodology**	**Purpose**	**Acceptance Criteria**	**Results**
Sterilization Cycle Validation	ISO 17665-2:2009 ANSI/AAMI/ISO 17665-1:2006/ (R)2013 ANSI / AAMI ST77:2013	To validate that the trays can be sterilized via moist-heat sterilization as specified on labeling (132° C for 4 minutes)	Sterility assurance level (SAL) of ≤ 10-6	Pass
Drying Validation	Internal Test Method	To validate that the trays can be dried as specified on labeling (drying time of 20 minutes)	No visible moisture	Pass
Cleaning (Manual Pre- Cleaning and Automated Cleaning)	AAMI TIR30:2011	To validate that the trays can be cleaned as specified on labeling	No visible soil. Protein: < 6.4 µg/cm^2 Hemoglobin: < 2.2 µg/cm^2	Pass
Reprocessing of Trays (cleaning and sterilization)	Internal Test Method	To confirm that the trays can be reprocessed as specified on labeling (up to 100 reprocessing cycles without any signs of abrasion)	No signs of flush rust, rust, corrosion, deformation or damage	Pass

SUMMARY DISCUSSION OF CLINICAL DATA

Non-clinical test data are submitted to support this premarket notification. No clinical studies are submitted.

CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the proposed device, K242023, is as safe, as effective, and performs as well as or better than the predicate device, K012105.