November 14, 2025

Paragon Implant Mfg., LLC
Renee Bennett
Regulatory Affairs Manager
27030 Malibu Hills Road
Calabasas, California 91301

Re: K251756
Trade/Device Name: Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 15, 2025
Received: October 16, 2025

Dear Renee Bennett:

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: 2025.11.14 16:27:56 -05'00'

Stephen Anisko
Acting Assistant 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)*
K251756

Device Name
Sterilization Trays

Indications for Use *(Describe)*
The Sterilization Trays are designed to hold various dental surgical and prosthetic instruments to organize, steam sterilize and transport the instruments between uses. The kit is to be enclosed in an FDA cleared steam sterilizable pouch large enough to fit a tray, and sterilized in an FDA cleared sterilizer for the following cycles:

1. Gravity Steam Cycle – At 132°C for 15 minutes with a 30-minute dry time
2. Pre-vacuum Steam Cycle – At 132°C for 4 minutes with a 20-minute dry time

* The kits are intended for sterilization of non-porous loads
* The tested kit represents the worst-case validated load of 497.1 grams

Model Name	Model (Catalog) Number	Max # of Instruments	Total Mass (g)	Vent to Volume Ratio (cm-1)
Complete Surgical Kit	CSK	55	497.1	0.01043
Standard Surgical Kit	SSK	N/A	372.1	0.01043
Drill Stop Kit	DSK	20	37.5	0.9009
Drill Stop Kit Empty	Not available	N/A	31.2	0.9009
Prosthetic Kit Empty	PKE	N/A	120.3	0.03324
Prosthetic Kit	Not available	20	497.1	0.03324

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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510(k) Summary
Paragon Implant Mfg., LLC
Sterilization Tray
November 13, 2025

Manufacturer Name	Paragon Implant Mfg., LLC 27030 Malibu Hills Road Calabasas, CA 91301, U.S.A. Telephone: (818) 475-4675
Official Contact	Renee Bennett, Manager of Regulatory Affairs Paragon Implant Mfg., LLC 27030 Malibu Hills Road Calabasas, CA 91301, U.S.A. Telephone: (818) 475-4675 Email: rbennett@paragon-implant.com

Device Name and Classification

Trade/Proprietary Name	Sterilization Tray
Common Name	Sterilization Wrap
Regulation Number	21 CFR § 880.6850
Regulation Name	Sterilization wrap (pack, sterilization wrapper, bag, or accessories)
Regulatory Class	Class II
Product Code(s)	KCT

Legally Marketed Predicate Device

Predicate Device Name	Standard Sterilizable Tray
510(k) Number:	K202524
Product Code:	KCT
Regulation Number:	21 CFR § 880.6850

Device Description

Paragon sterilization trays are divided into the following types:

- Complete Surgical Kit
- Standard Surgical Kit
- Drill Stop Kit
- Prosthetic Kit

The Surgical, Drill Stop, and Prosthetic Kits are reusable perforated instrument cassette systems, composed of an outer case (base), cover (lid), and insert, that is designed to hold dental instruments in place during transport, steam sterilization, and storage. The Surgical Kits are designed to support Paragon

implant/prosthetic placement protocols, as well as hold various dental instruments such as: Surgical Drills, Drill Stops, Paralleling Tools, Implant Drivers, Drill Extender, Prosthetic Drivers and Torque Wrenches.

The insert contains markings and colors to indicate either the surgical workflow or the position of the instruments within the cassette.

The Standard Surgical Kit includes a removable stainless-steel pan, which functions as a storage receptacle for used surgical instruments.

Indications for Use Statement
The Sterilization Trays are designed to hold various dental surgical and prosthetic instruments to organize, steam sterilize and transport the instruments between uses. The kit is to be enclosed in an FDA cleared steam sterilizable pouch large enough to fit a tray, and sterilized in an FDA cleared sterilizer for the following cycles:

1. Gravity Steam Cycle – At 132°C for 15 minutes with a 30-minute dry time
2. Pre-vacuum Steam Cycle – At 132°C for 4 minutes with a 20-minute dry time

- The kits are intended for sterilization of non-porous loads
- The tested kit represents the worst-case validated load of 497.1 grams

Model Name	Model (Catalog) Number	Max # of Instruments	Total Mass (g)	Vent to Volume Ratio (cm^{-1})
Complete Surgical Kit	CSK	55	497.1	0.01043
Standard Surgical Kit	SSK	N/A	372.1	0.01043
Drill Stop Kit	DSK	20	37.5	0.9009
Drill Stop Kit Empty	Not available	N/A	31.2	0.9009
Prosthetic Kit Empty	PKE	N/A	120.3	0.03324
Prosthetic Kit	Not available	20	497.1	0.03324

Comparison of Technological Characteristics:

Table 1. Technological Characteristics Comparison Table

Characteristic	Subject Device (K251756)	Predicate Device K202524 (Standard Sterilizable Tray)	Comparison
Manufacturer/ Device Applicant	Paragon Implant Mfg, LLC 27030 Malibu Hills Road Calabasas, CA 91301-5332	Implant Direct Sybron Manufacturing, LLC 3050 East Hillcrest Drive Thousand Oaks, CA 91362	Different
Trade/Device Name	Sterilization Trays	Standard Sterilizable Tray	Different
Regulation Number	880.6850 (Sterilization Wrap)	880.6850 (Sterilization Wrap)	Same
Classification	2	2	Same
Primary Product Code	KCT	KCT	Same
Indications for Use	The Sterilization Trays are designed to hold various dental surgical and prosthetic instruments to organize, steam sterilize and transport the instruments between uses. The kit is to be enclosed in an FDA cleared steam sterilizable pouch large enough to fit a tray, and sterilized in an FDA cleared sterilizer for the following cycles: 3. Gravity Steam Cycle – At 132°C for 15 minutes with a 30-minute dry time 4. Pre-vacuum Steam Cycle – At 132°C for 4 minutes with a 20-minute dry time • The kits are intended for sterilization of non-porous loads • The tested kit represents the worst-case validated load of 497.1 grams	The Standard 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 (maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles: (1) Prevacuum 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 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 667.52 grams. - Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Standard Sterilizable Tray.	Same Differences: • Maximum number instruments, total mass, vent to volume ratio information itemized in separate columns below.

<table>
<tr><th>Characteristic</th><th>Subject Device
(K251756)</th><th>Predicate Device
K202524 (Standard Sterilizable Tray)</th><th>Comparison</th></tr>
<tr><td></td><td>
<table>
<tr><th>Model Name</th><th>Model (Catalog) Number</th><th>Max # of Instruments</th><th>Total Mass (g)</th><th>Vent to Volume Ratio (cm-1)</th></tr>
<tr><td>Complete Surgical Kit</td><td>CSK</td><td>55</td><td>497.1</td><td>0.01043</td></tr>
<tr><td>Standard Surgical Kit</td><td>SSK</td><td>N/A</td><td>372.1</td><td>0.01043</td></tr>
<tr><td>Drill Stop Kit</td><td>DSK</td><td>20</td><td>37.5</td><td>0.9009</td></tr>
<tr><td>Drill Stop Kit Empty</td><td>Not available</td><td>N/A</td><td>31.2</td><td>0.9009</td></tr>
<tr><td>Prosthetic Kit Empty</td><td>PKE</td><td>N/A</td><td>120.3</td><td>0.03324</td></tr>
<tr><td>Prosthetic Kit</td><td>Not available</td><td>20</td><td>497.1</td><td>0.03324</td></tr>
</table>
</td><td>
<table>
<tr><th>Model Name</th><th>Model Number</th><th>Max # of Instruments</th><th>Max Load (g)</th><th>Vent to volume Ratio (in^{-1})</th></tr>
<tr><td>Standard Surgical Kit</td><td>CSSK</td><td>46</td><td>667.52</td><td>0.021</td></tr>
<tr><td>Standard Surgical Kit Empty</td><td>SSK</td><td></td><td>385.2</td><td>0.021</td></tr>
<tr><td>InterActive™ Surgical Kit</td><td>CISK</td><td>34</td><td>662.70</td><td>0.021</td></tr>
<tr><td>InterActive™ Surgical Kit Empty</td><td>ISK</td><td></td><td>384.2</td><td>0.021</td></tr>
</table>
</td><td></td></tr>
<tr><td>Materials</td><td>
<table>
<tr><td>CSK:</td><td>Base: Radel® R-5000 NT
Lid: Radel® R-5000 NT
Inner Tray: Radel® R-5000 NT
Tooling Support: Silicone
DSK: (see DSK)</td></tr>
<tr><td>SSK:</td><td>Base: Radel® R-5000 NT
Lid: Radel® R-5000 NT
Inner Tray: Radel® R-5000 NT
Tooling Support: Silicone
Pan: Stainless Steel</td></tr>
<tr><td>DSK:</td><td>Lid: Radel® R-5000 NT
Base: PPHT</td></tr>
<tr><td>PKE:</td><td>Lid: Radel® R-5000 NT
Base: Radel® R-5000 NT</td></tr>
</table>
</td><td>Base – Radel 5000
Lid – Radel 5000
Inner tray – Radel 5000
Tooling support - Silicone
Pan – Stainless steel</td><td>Same:
• Radel® R-5000 NT, Silicone, and Stainless Steel

Differences:
• The Drill Stop Kit (DSK) base is made from PPHT.</td></tr>
<tr><td>Maximum Number of Devices</td><td>CSK: 55
DSK: 20</td><td>CSSK: 46
CISK: 34</td><td>Differences:
• Subject (55) maximum number of</td></tr>
</table>

Characteristic	Subject Device (K251756)	Predicate Device K202524 (Standard Sterilizable Tray)	Comparison
			devices is more than the predicate (46)
Mass of Maximum Sterilization Load	CSK: 497.1g SSK: 372.1g DSK: 37.5g PKE: 497.1g	CSSK: 667.52g CISK:662.70g	Differences: • Subject (497.1g) mass of maximum sterilization load is less than the predicate (667.52g)
Vent to Volume Ratio	CSK: $0.01043 cm^{-1}$ ($0.004106 in^{-1}$) SSK: $0.01043 cm^{-1}$ ($0.004106 in^{-1}$) DSK: $0.9009 cm^{-1}$ ($0.3547 in^{-1}$) PKE: $0.03324 cm^{-1}$ ($0.01309 in^{-1}$)	CSSK: $0.021\ in^{-1}$ CISK: $0.021\ in^{-1}$	Differences: • Subject ($0.004106 in^{-1}$) is lower than the predicate ($0.021\ in^{-1}$) vent to volume ratio
Air Permeance	Yes	Yes	Same
Intended Use	Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage	Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage	Same
General Design	Plastic tray with locking lid, silicone grommet supports, stainless steel pan (SSK only)	Plastic tray with locking lid co-molded silicone and silicone grommet supports and stainless steel component	Same
Dimensions	CSK & SSK: 185.1mm x 133.8mm x 59mm (7.29” x 5.27” x 2.32”) DSK: 64mm x 43mm x 26.5mm (2.52” x 1.69” x 1.04”) PKE: 145mm x 100mm x 18mm (5.71”x 3.94” x 0.71”)	7.3 in x 5.5 in x 2.4 in	Differences: • Predicate tray is slightly larger than the subject trays
Sterility	Non-Sterile	Non-Sterile	Same
Sterilization Method	Moist heat gravity or pre-vacuum	Moist heat gravity or pre vacuum	Same
Usage	Reusable	Reusable	Same

Indication for Use Comparison

The indications for use are the same as the predicate.

Comparison to Legally Marketed Predicate Device

The subject Sterilization Trays and the predicate K202524 (Standard Sterilizable Tray) are similar in general design composed of a plastic tray with a locking lid, Silicon overmolded accessories (co-molded Silicone and Silicone Grommet supports), and Stainless-Steel pan. The subject Sterilizable Tray (specifically the Complete Surgical Kit) has an inserted kit (container) for holding Drill Stops which the predicate K202524 (Standard Sterilizable Tray) does not.

The subject Sterilizable Trays and predicate K202524 (Standard Sterilizable Tray) device have the same intended use.

The subject Sterilizable Trays are slightly smaller in size than the predicate K202524 (Standard Sterilizable Tray) and are the same materials except for the Drill Stop container base. Although the materials are not intended to contact the patient, they are in contact with surgical and prosthetic instruments and handled by clinicians. Provided testing reports show the minimum biocompatibility endpoints for the subject devices have no risk of the materials migrating during containment and sterilization. The use of Sterilization Trays has been validated through sterilization testing.

The subject Sterilizable Trays and predicate K202524 (Standard Sterilizable Tray) devices are sold non-sterile are reusable devices. They require the same end user sterilization methods (most heat gravity or pre-vacuum) when using as intended as a sterilization wrap.

The vent to volume ratio for the subject Sterilization Trays is 0.01043 cm^{-1} (0.027 in^{-1}) which is higher than the predicate (0.021 in^{-1}) vent to volume ratio and this has been demonstrated to not present an issue through sterilization validation testing.

The subject Sterilization Tray loaded with the maximum number of devices can hold more instruments and has a smaller maximum sterilization load than the predicate K202524 (Standard Sterilizable Tray). The maximum sterilization load for the subject Sterilization Tray is 497.1g, while the predicate's maximum sterilization load is 667.52g. While the subject Sterilization Tray has a smaller weight and more instruments, this has been demonstrated to not be an issue through sterilization testing and has been validated.

Summary of Non-Clinical Testing

The proposed Surgical and Prosthetic Trays are reusable devices provided non-sterile which need to be end user sterilized. Sterilization of the proposed trays was validated according to the FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". Non-clinical testing data submitted, referenced, or relied upon, including acceptance criteria and set specifications in test methodology and standards, are summarized below:

- Manual Cleaning Validation:
    - Standards: AAMI TIR12:2020, AAMI ST98:2022, ISO 17664-1:2021, and 2015 FDA Guidance Document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

  - Purpose: Evaluate and validate the manual cleaning of the subject devices
  - Acceptance Criteria: No visible soil should remain on the test articles. Protein level should be <6.4 µg/cm2 for the processed test articles
  - Result: Pass
- Automated Cleaning Validation:
  - Standards: AAMI TIR12:2020, AAMI ST98:2022 and 2015 FDA Guidance Document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*
  - Purpose: Evaluate and validate the automated cleaning of the subject devices
  - Acceptance Criteria: No visible soil should remain on the test articles. Protein level should be <6.4 µg/cm2 for the processed test articles.
  - Result: Pass
- Gravity and Prevacuum Steam Sterilization Validation
  - Standards: ISO 17665:2024, ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D and the validation approach outlined in ANSI/AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3), and AAMI TIR12:2020
  - Purpose: Validate a sterilization cycle and drying time of the subject devices
  - Acceptance Criteria: SAL $\leq 10^{-6}$ using the biological indicator (BI) overkill method
  - Result: Pass
- Biocompatibility Testing
  - Test Methodology/Standard: ISO 10993-5 and the FDA Guidance Use of International Standard ISO 10993-1
  - Purpose: Cytotoxicity testing has been performed to validate the biocompatibility of the standard surgical, prosthetic, and drill stop kits which shows that the materials and manufacturing processes represented by the finished subassemblies are non-cytotoxic following cleaning and sterilization.
  - Acceptance Criteria: Reagent control and the negative control must have a reactivity of none (grade 0), and the positive control must be a grade 3 or 4. The test sample must meet the requirements of the test if the biological response is less than or equal to grade 2 (mild).
  - Result: Pass

Clinical Performance Data
Not applicable.

Conclusions
The conclusions drawn from the non-clinical test data and evaluation support that the proposed Sterilization Trays are as safe, as effective and perform as well as the legally marketed predicate device K202524 (Standard Sterilizable Tray).