June 13, 2019

Paragon Medical
C/o Rebecca Walker
Regulatory Affairs Manager
8 Matchett Dr
Pierceton, Indiana 46562

Re: K190667
Trade/Device Name: Sonopet iQ Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: May 7, 2019
Received: May 8, 2019

Dear Rebecca Walker:

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 Elizabeth F. Claverie-Williams, MS
Assistant Director,
THT4B2: Disinfection Reprocessing and Personal Protection
Acting Assistant Director,
THT4B1: Sterility Devices
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)*

K190667

Device Name

Sonopet iQ Sterilization Tray

Indications for Use *(Describe)*

The Sonopet iQ Sterilization Tray is intended to enclose and organize Stryker Sonopet iQ reusable medical instruments during processing at a healthcare facility. The trays are not intended to maintain sterility; they are intended to be used in conjunction with a legally marketed, FDA-cleared sterilization wrap or rigid container in order to maintain sterility of the enclosed devices. The Sonopet iQ Sterilization Tray is intended for use in any of the following standard sterilization cycles:

Method	Parameter	Cycle	
Pre-vacuum Steam		**Cycle 1**	**Cycle 2**
	Enclosure	Double Wrap or Rigid Container	Double Wrap or Rigid Container
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	4 minutes	3 minutes
	Dry Time	30 minutes	30 minutes

The maximum product load for the tray is as follows:

Tray Description	Catalog Number	Maximum Tray Product Load	Maximum Tray Weight
Sonopet iQ Sterilization Tray	5500-800-278	Handpiece (Qty 1) Cleaning Wire (Qty 1) Torque Wrench (Qty 1)	6.85 lb

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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PARAGON MEDICAL

8 Matchett Drive • Pierceton, IN 46562 • 800.225-6975 • Fax: 574.594.2154 • www.paragonmedical.com

510(k) Summary for Sonopet iQ Sterilization Tray, K190667

In accordance with 21 CFR 807.92, the following 510(k) summary is provided:

1. **Applicant Information:**
   Paragon Medical
   8 Matchett Drive
   Pierceton, IN 46562 USA
   Phone: 574-594-2140
   Fax: 574-594-2154

2. **Correspondent Contact Information:**
   Jill Bouillon
   Quality Manager
   Jill.bouillon@nninc.com
   Phone: 574-594-2140 ext. 10403

3. **Date Prepared:** June 12, 2019

4. **Trade Name:** Sonopet iQ Sterilization Tray

5. **Common Name:** Sterilization Tray

6. **Classification Name:** Sterilization wrap containers, trays, cassettes and other accessories (21 CFR 880.6850, Product Code KCT)

7. **Predicate Device:** Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray and Camera Sterilization Tray, K152951

8. **Device Description:** The Sonopet iQ Sterilization Tray is a reusable device manufactured of perforated stainless steel for the base and lid to allow for sterilization of the enclosed devices. The tray is used to enclose and organize Stryker Sonopet iQ reusable medical instruments during processing at a healthcare facility. The tray is compatible with pre-vacuum steam sterilization. The tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, FDA-cleared sterilization wrap or rigid container in order to maintain sterility of the enclosed devices. The tray is provided in a non-sterile condition, and must be sterilized prior to use.

9. **Indications for Use:** The Sonopet iQ Sterilization Tray is intended to enclose and organize Stryker Sonopet iQ reusable medical instruments during processing at a healthcare facility. The trays are not intended to maintain sterility; they are intended to be used in conjunction with a legally marketed, FDA-cleared sterilization wrap or rigid container in order to maintain sterility of the enclosed devices. The Sonopet iQ Sterilization Tray is intended for use in any of the following standard sterilization cycles:

Method	Parameter	Cycle	
Pre-vacuum Steam		**Cycle 1**	**Cycle 2**
	Enclosure	Double Wrap or Rigid Container	Double Wrap or Rigid Container
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	4 minutes	3 minutes
	Dry Time	30 minutes	30 minutes

The maximum product load for the tray is as follows:

Tray Description	Catalog Number	Maximum Tray Product Load	Maximum Tray Weight
Sonopet iQ Sterilization Tray	5500-800-278	Handpiece (Qty 1) Cleaning Wire (Qty 1) Torque Wrench (Qty 1)	6.85 lb

10. **Technological Characteristics:** The following pages contain a detailed comparison of the subject device to the predicate comparison of the technological (Table 1) and performance (Table 2) characteristics of the subject and predicate device.

Table 1: Comparison of Technological Characteristics

<table>
<tr><th></th><th>Predicate Device (K152951)</th><th>Subject Device (K190667)</th></tr>
<tr><td>Device Name</td><td>Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray and Camera Sterilization Tray</td><td>Sonopet iQ Sterilization Tray</td></tr>
<tr><td>Manufacturer</td><td>Paragon Medical
8 Matchett Dr
Pierceton, IN 46562</td><td>Paragon Medical
8 Matchett Dr
Pierceton, IN 46562</td></tr>
<tr><td>510(k) Number</td><td>K152951</td><td>K190667</td></tr>
<tr><td>Product Code</td><td>KCT</td><td>KCT</td></tr>
<tr><td>Design</td><td>The trays (stainless steel base with a removable stainless steel lid) have an evenly distributed perforated steam hole pattern to facilitate sterilant/steam penetration.
The base includes silicone brackets for Stryker endoscopy device fixation within the tray and two (2) latches to affix the lid to the base. Handles on the sides of the base facilitate carrying of the tray. The trays are reusable and provided in a non-sterile condition.</td><td>The trays (stainless steel base with a removable stainless steel lid) has an evenly distributed perforated steam hole pattern to facilitate sterilant/steam penetration.
The base includes stainless steel and silicone brackets for device fixation within the tray and two (2) stainless steel latches to affix the lid to the base. Two retractable handles on the sides of the base facilitate carrying of the tray. The trays are reusable and provided in a non-sterile condition.</td></tr>
<tr><td>Materials</td><td>Stainless Steel, Silicone</td><td>Stainless Steel, Silicone, Thermoplastic Polymers</td></tr>
<tr><td>Indications for Use</td><td>The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended to enclose and organize Stryker Endoscopy reusable medical instruments during sterilization at a healthcare facility. The trays are optional accessories to the Stryker Endoscopy instruments for which they are designed. The trays are not intended to maintain sterility; they are intended to be used in conjunction with legally marketed, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended for use in any of the following standard sterilization machines / cycles:
<table>
<tr><th>Method</th><th colspan="3">Cycle</th></tr>
<tr><td rowspan="13">Ethylene Oxide (EtO)</td><td colspan="3">Preconditioning Parameters</td></tr>
<tr><td>Temperature (°C)</td><td colspan="2">55°C (131°F)</td></tr>
<tr><td>Chamber Humidity</td><td colspan="2">70% RH</td></tr>
<tr><td>Vacuum Set Points</td><td colspan="2">1.3 psia</td></tr>
<tr><td>Time</td><td colspan="2">30 minutes</td></tr>
<tr><td colspan="3">Exposure</td></tr>
<tr><td>Concentration</td><td colspan="2">725 mg/L, 100% EO</td></tr>
<tr><td>Temperature (°C)</td><td colspan="2">55°C ±2°C (131°F ±5°F)</td></tr>
<tr><td>Time</td><td colspan="2">1 hour</td></tr>
<tr><td>Chamber Humidity (%)</td><td colspan="2">70% RH (50-80%) ±5%</td></tr>
<tr><td colspan="3">Aeration</td></tr>
<tr><td>Aeration Time</td><td colspan="2">12 hours</td></tr>
<tr><td>Temperature</td><td colspan="2">35°C - 54°C (95°F – 129°F)</td></tr>
<tr><td rowspan="4">Pre-vacuum Steam</td><td></td><td>Cycle 1</td><td>Cycle 2</td></tr>
<tr><td>Wrapping</td><td>Double</td><td>Double</td></tr>
<tr><td>Temperature</td><td>132°C (270°F)</td><td>134°C (273°F)</td></tr>
<tr><td>Sterilization Time</td><td>4 minutes</td><td>3 minutes</td></tr>
</table>
The Sonopet iQ Sterilization Tray is intended to enclose and organize Stryker Sonopet iQ reusable medical instruments during processing at a healthcare facility. The tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, FDA-cleared sterilization wrap or rigid container in order to maintain sterility of the enclosed devices. The Sonopet iQ Sterilization Tray is intended for use in any of the following standard sterilization cycles:
<table>
<tr><th>Method</th><th>Parameter</th><th colspan="2">Cycle</th></tr>
<tr><td rowspan="4">Pre-vacuum Steam</td><td></td><td>Cycle 1</td><td>Cycle 2</td></tr>
<tr><td>Enclosure</td><td>Double Wrap or Rigid Container</td><td>Double Wrap or Rigid Container</td></tr>
<tr><td>Temperature</td><td>132°C (270°F)</td><td>134°C (273°F)</td></tr>
<tr><td>Sterilization Time</td><td>4 minutes</td><td>3 minutes</td></tr>
<tr><td>Dry Time</td><td>30 minutes</td><td>30 minutes</td></tr>
</table>
The maximum product load for the tray is as follows:
<table>
<tr><th>Catalog Number</th><th>Maximum Tray Product Load</th><th>Maximum Tray Weight</th></tr>
<tr><td>5500-800-278</td><td>Handpiece (Qty 1)
Torque Wrench (Qty 1)
Cleaning Wire (Qty 1)</td><td>6.85 lb.</td></tr>
</table></td></tr>
</table>

	Dry Time	30 minutes	30 minutes
Gravity Steam		**Cycle 1**	**Cycle 2**
	Wrapping	Double	Double
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	15 minutes	10 minutes
	Dry Time	30 minutes	30 minutes

Method	**Cycle**
STERIS® V-PRO® 1	Standard
STERIS® V-PRO® 1 Plus	Non-Lumen or Lumen
STERIS® V-PRO® maX	Non-Lumen or Lumen
STERRAD® 100S	Standard
STERRAD® NX®	Standard
STERRAD® 100NX®	Standard

In addition, the Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are validated for the following Immediate Use Steam Sterilization cycles for emergency situations ONLY:

Immediate Use Steam Sterilization ("Flash") Pre-vacuum Steam		**Cycle 1**	**Cycle 2**
	Wrapping	None	None
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	4 minutes	3 minutes
	Dry Time	None	None

The maximum product loads for the trays are as follows:

Tray Description	**Catalog Number**	**Max Tray Product Load**	**Total Loaded Tray Weight**
Advanced Imaging Modality Sterilization (AIM) Tray	0233-032-301	Camera (Qty 1) Light Cable (Qty 1) Coupler (Qty 1) Scope (Qty 2) Adapter (Qty 2)	10.58 lbs
Endoscope and Camera Sterilization Tray	0233-032-302	Camera (Qty 1) Light Cable (Qty 1) Coupler (Qty 1) Scope (Qty 2) Adapter (Qty 2)	10.58 lbs
Camera Sterilization Tray	0233-410-002	Camera (Qty 1) Light Cable (Qty 1) Coupler (Qty 1)	8.83 lbs

Configuration and Dimensions	AIM/Endoscope and Camera Trays: 21.2 x 10.5 x 2.9 inches Camera Tray: 15.6 x 10.5 x 2.9 inches	9.80 x 9.80 x 2.87 inches
Percent of Surface Perforations	AIM/Endoscope and Camera Trays: 10.3% Camera Tray: 9.9 %	12.41%

Sterilization Method	Pre-vacuum Steam, Pre-Vacuum Steam Immediate Use (Flash), Gravity Steam, STERRAD 100S, STERRAD NX, STERRAD 100NX, Steris V-PRO, Steris V-PRO 1 Plus, Steris V-PRO 1 maX, Ethylene Oxide	Pre-vacuum Steam
Single Use/ Reusable	Reusable	Reusable
Sterilization Barrier	Sterilization Wrap	Sterilization Wrap Rigid Container
Patient Contact	No direct patient contact	No direct patient contact

Table 2: Comparison of Performance Characteristics

	Predicate Device (Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray and Camera Sterilization Tray)	**Subject Device** (Sonopet iQ Sterilization Tray)
Material Compatibility with Sterilization Process	Materials are compatible with indicated sterilization methods. Performance testing demonstrated that the materials of construction are compatible with repeated sterilization cycles.	Same
Toxicological Properties	Cytotoxicity testing demonstrated that the materials are non-cytotoxic.	Same
Life cycle Testing	Life cycle testing to 100 worst-case processing cycles showed no visual degradation or alteration to form, function or operation of the tray	Same
Design Verification	Handle Strength testing met the requirements of ANSI/AAMI ST77:2013 and DIN EN 868-8:2009-09, Latch Force testing met requirements of ANSI/AAMI HE75:2009	Design verification testing included handle strength, latch force, stacking, and weight.

11. **Summary of Nonclinical Testing:** The following non-clinical performance testing were conducted on the Sonopet iQ Sterilization Tray:
    - **Sterilization and Dry Time Validation**
      Sterilization validations were performed to verify the effectiveness of steam sterilization of a fully loaded Sonopet iQ Sterilization Tray sterilized in a rigid sterilization container and double-wrapped with sterilization wrap. Tests were performed using an autoclave cycle with pre-vacuum air removal. The study evaluated the resistance of biological indicators (BIs) with 10^6 *Geobacillus stearothermophilus* spores to pre-vacuum steam autoclave half cycle exposures. Dry time was evaluated after sterilization. The Sonopet iQ Sterilization Tray was validated per ANSI/AAMI/ISO 17665-1.
    - **Cleaning Validation**
      A manual and automated cleaning validation was performed per AAMI TIR 30:2011 to validate the cleaning instructions. The results indicate that the recommended cleaning methods were effective in removing soil from all designated surfaces of the Sonopet iQ Sterilization Tray that might be accessible to the end user.

- **Biocompatibility**
  Biocompatibility testing was conducted on all materials used in construction of the Sonopet iQ Sterilization Tray per ISO 10993-5 using the MEM Elution method. Test article extracts showed grade 2 or less cell lysis and reactivity, indicating the materials met acceptable cytotoxicity levels.
- **Design Verification**
  Design verification testing included verification of the handle strength and weight per ANSI/AAMI ST77, stacking features per DIN EN 868-8, and latch force.
- **Life Cycle Testing**
  Life cycle testing was performed to verify that the Sonopet iQ Sterilization Tray maintained functional quality requirements, material integrity, and traceability (artwork and UDI legibility) after exposure to repeated pre-vacuum steam sterilization cycles, automated washing cycles and simulated functional use of the components, which included kitting the tray, latch and handle actuation).

  All results of performance testing met acceptance criteria.

12. **Conclusion:** Based on the intended use, technological characteristics, performance data, and nonclinical testing performed, the subject device is substantially equivalent to the legally marketed predicate device.