May 7, 2019

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

Re: K183701
Trade/Device Name: Stryker ChestShield Sterilization Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 3, 2019
Received: April 5, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 David Krause, PhD
Acting 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)*
K183701

Device Name

Stryker ChestShield Sterilization Tray System

Indications for Use *(Describe)*

The Stryker ChestShield Sterilization Tray System is intended to organize, enclose, sterilize, transport, and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker ChestShield Sterilization Tray System has been validated for use in the following sterilization cycle:

	Pre-vacuum Steam
Enclosure	Rigid Container
Temperature	132°C (270°F)
Sterilization Time	4 minutes
Minimum Dry Time	30 minutes
Maximum Weight[1]	19.23 lb. / 8.72 kg

[1]The validated load configuration for the Stryker ChestShield Sterilization Tray System included single-use implants (plates, bone screws, etc.), single-use instruments (drills), reusable surgical instruments (benders, forceps, drivers, etc.) and lumened instruments.

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

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510(k) Summary for Stryker ChestShield Sterilization Tray System, K183701

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:**
Rebecca Walker
Regulatory Affairs Manager
Rebecca.walker@nninc.com
Phone: 574-594-2140 ext. 10384

3. **Date Prepared:** May 2, 2019

4. **Trade Name:** Stryker ChestShield Sterilization Tray System

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:** Stryker Universal Select Sterilization Tray System, K173615

8. **Device Description:** The Stryker ChestShield Sterilization Tray System is a tray system designed to store implants and surgical instrumentation. The tray system consists of an anodized aluminum implant module with an inlay which stores the implantable components and stainless steel instrument trays, which have stainless steel and silicone brackets to contain the reusable and single-use instruments. Both the implant module and instrument trays have laser-etched and silkscreened artwork to assist the end user in correct placement of the contents. The tray components have stainless steel lids which feature a slide latch. The trays and implant module are organized and stored in a stainless steel rack. The tray system does not maintain sterility; the rack is placed in a rigid sterilization container to act as a sterile barrier for sterilization. The tray system provided in a non-sterile condition and must be sterilized prior to and after each use.

9. **Indications for Use:** The Stryker ChestShield Sterilization Tray System is intended to organize, enclose, sterilize, transport, and store Stryker implantable devices and surgical instruments within a

healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker ChestShield Sterilization Tray System has been validated for use in the following sterilization cycle:

	Pre-vacuum Steam
Enclosure	Rigid Container
Temperature	132°C (270°F)
Sterilization Time	4 minutes
Minimum Dry Time	30 minutes
Maximum Weight[1]	19.23 lb. / 8.72 kg

[1]The validated load configuration for the Stryker ChestShield Sterilization Tray System included single-use implants (plates, bone screws, etc.), single-use instruments (drills), reusable surgical instruments (benders, forceps, drivers, etc.) and lumened instruments.

10. Technological Characteristics:

Shown below is a comparison of the technological (Table 1) and performance (Table 2) characteristics of the subject and predicate device.

Table 1: Technological Characteristics

	Predicate Device	**Subject Device**	**Comparison**
Device Name	Stryker Universal Select Sterilization Tray System	Stryker ChestShield Sterilization Tray System	--
510(k) Number	K173615	K183701	--
Product Code	KCT	KCT	Same
Indications for Use	The Stryker Universal Select Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker Universal Select Sterilization Tray System has been validated for use in the following sterilization cycles:	The Stryker ChestShield Sterilization Tray System is intended to organize, enclose, sterilize, transport, and store Stryker implantable devices and surgical instruments within a healthcare facility when used in conjunction with a validated, FDA cleared rigid sterilization container in order to maintain sterility of the enclosed devices. The Stryker ChestShield Sterilization Tray System has been validated for use in the following sterilization cycle:	Similar Differences include maximum weight and validated load contents

	Pre-vacuum Steam Cycles	
Enclosure	Rigid Container	Rigid Container
Temperature	132°C (270°F)	135°C (275°F)
Sterilization Time	4 min	3 min
Minimum Dry Time	30 min	30 min
Maximum Weight[1]	25 lb./ 11.36kg	25 lb./ 11.36kg

[1]Contents in the validated Tray System included: Single-use implants (plates, meshes, bone screws, etc.), single-use instruments (drills), and reusable surgical instruments (benders, forceps, handles, depth gauges, trocars, etc.)

	Pre-Vacuum Steam Cycle
Enclosure	Rigid Container
Temperature	132°C (270°F)
Sterilization Time	4 min
Minimum Dry Time	30 min
Maximum Weight[1]	19.23 lb. / 8.72 kg

[1]The validated load configuration for the Stryker ChestShield Sterilization Tray System included single-use implants (plates, bone screws, etc.), single-use instruments (drills), reusable surgical instruments (benders, forceps, drivers, etc.) and lumened instruments.

Table 1 (continued): Technological Characteristics

<table>
<tr><th></th><th>Predicate Device</th><th>Subject Device</th><th>Comparison</th></tr>
<tr><td>Intended Use</td><td>The Stryker Universal Select Sterilization Tray System is intended to organize, enclose, sterilize, transport, and store medical devices between surgical uses in a healthcare facility.</td><td>The Stryker ChestShield Sterilization Tray System is intended to organize, enclose, sterilize, transport, and store medical devices between surgical uses in a healthcare facility.</td><td>Same</td></tr>
<tr><td>Design</td><td>The Stryker Universal Select Sterilization Tray System platform is designed to be compatible with Stryker implantable devices and surgical instrumentation. Individual components were designed to slide in to two and three level storage racks. Racks have handles on the side to facilitate carrying. Module and tray lids have sliding latch mechanism to facilitate containment.</td><td>The design of the Stryker ChestShield Sterilization Tray System is the same as the predicate device, with specific instrument brackets and implant module layout for the intended Stryker surgical instrumentation and implantable devices. The individual tray components slide into the existing two-level storage rack part of the predicate device system.</td><td>Similar

Differences include specific bracket, implant module and inlay layouts</td></tr>
<tr><td>Principles of Operation</td><td>Operates on the principles of allowing steam penetration through perforations and open area designed into the components to achieve sterilization of the contained devices.</td><td>Operates on the principles of allowing steam penetration through perforations and open area designed into the components to achieve sterilization of the contained devices.</td><td>Same</td></tr>
<tr><td>Materials of Construction</td><td>Stainless Steel, Anodized Aluminum, USP Class VI Silicone, Thermoplastic Polymers</td><td>Same as predicate</td><td>Same</td></tr>
<tr><td>Sterilization Parameters</td><td><table><tr><th>Cycle</th><th>Temp</th><th>Exposure</th><th>Min Dry Time</th></tr><tr><td rowspan="2">Pre-Vacuum</td><td>132° C (270°F)</td><td>4 Min</td><td>30 Min</td></tr><tr><td>135°C (275°F)</td><td>3 Min</td><td>30 Min</td></tr></table></td><td><table><tr><th>Cycle</th><th>Temp</th><th>Exposure</th><th>Min Dry Time</th></tr><tr><td>Pre-Vacuum</td><td>132°C (270°F)</td><td>4 Min</td><td>30 Min</td></tr></table></td><td>Similar</td></tr>
<tr><td>Perforations</td><td>Evenly distributed perforated steam hole pattern.</td><td>Evenly distributed perforated steam hole pattern.</td><td>Same</td></tr>
<tr><td>Vent to Volume ratio</td><td>The predicate Stryker Universal Select Sterilization Tray System components have the following worst-case vent to volume ratios:<table><tr><th>Paragon Part Number</th><th>Stryker Part Number</th><th>Description</th><th>Vent to Volume Ratio</th></tr><tr><td>3009-1013</td><td>29-13904</td><td>Mandible Fracture Instrument Tray with Lid (3349-0006/29-13921)</td><td>0.321</td></tr><tr><td>2209-0109</td><td>29-23900</td><td>2.0/2.3 Mandible Screws Module with Lid (3349-0005/29-13941)</td><td>0.054</td></tr><tr><td>2219-0036</td><td>29-17903</td><td>1.7 Orthognathic Plates Inlay</td><td>0.265</td></tr><tr><td>3009-1008</td><td>29-13900</td><td>2-Level Rack</td><td>0.297</td></tr></table></td><td>The subject Stryker ChestShield Sterilization Tray System components have the following worst-case vent to volume ratios:<table><tr><th>Paragon Part Number</th><th>Stryker Part Number</th><th>Description</th><th>Vent to Volume Ratio</th></tr><tr><td>3009-1040</td><td>4700002</td><td>SternalPlate Instrument Tray 2 with Lid (3349-0009/4700101)</td><td>0.330</td></tr><tr><td>2209-0115</td><td>4700201</td><td>SternalPlate Implant Module with Lid (3349-0008/4700102)</td><td>0.082</td></tr><tr><td>2219-0002</td><td>4700202</td><td>SternalPlate Plates Inlay</td><td>0.288</td></tr></table></td><td>Similar</td></tr>
<tr><td>Sterilization Method</td><td>Pre-vacuum Steam</td><td>Pre-vacuum Steam</td><td>Same</td></tr>
<tr><td>Reusable</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Patient Contact</td><td>No direct patient contact</td><td>No direct patient contact</td><td>Same</td></tr>
<tr><td>Air Permeance</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
</table>

Configuration and Dimensions of Device Models	Two-level Rack	9.80 x 9.70 x 5.27”	Two-level Rack[1]	9.80 x 9.70 x 5.27”	Similar
	Three level Rack	9.80 x 9.70 x 7.57”			
	¼ DIN Inst/Accessory Tray	9.31 x 4.09 x 1.54”	¼ DIN Instrument Tray	9.31 x 4.09 x 1.54”	Differences include slight dimensional differences in the inlay of the subject device to accommodate the intended implants.
	¼ DIN Inst/Accessory Tray Lid	9.29 x 4.30 x 0.49”	¼ DIN Instrument Tray Lid	9.21 x 4.30 x 0.49”	
	½ DIN Inst/Accessory Tray	9.31 x 8.55 x 1.54”			
	½ DIN Inst/Accessory Tray Lid	9.29 x 8.71 x 0.55”			
	¼ DIN Implant Module	9.31 x 4.25 x 1.05”			
	¼ DIN Screw Module	9.31 x 4.25 x 1.75”	¼ DIN Implant/Screw Module	9.31 x 4.25 x 1.75”	
	¼ DIN Implant Module Lid	9.33 x 4.22 x 0.44”	¼ DIN Implant Module Lid	9.33 x 4.22 x 0.44”	
	Inlay	4.34 x 3.85 x 0.53”	Inlay	4.09 x 3.31 x 0.63”	
	Inlay, large	8.91 x 3.85 x 0.34”			
	Drill Caddy	3.30 x 1.33 x 1.47”			
	¼ DIN Silicone Mat	8.95 x 3.67 x 0.63”	[1]Two-level Rack is identical to the predicate.		
	½ DIN Silicone Mat	8.95 x 8.14 x 0.63”			

Table 2: Performance Characteristics

	Predicate Device	**Subject Device**	**Comparison**
Material Compatibility with Sterilization Process	Predicate device is compatible with steam sterilization.	Subject device is compatible with steam sterilization.	Same
Biocompatibility	Cytotoxicity (ISO 10993-5) testing results demonstrated that the predicate device is non-cytotoxic	Subject device is identical in formulation and processing to the predicate device; therefore, cytotoxicity results of the predicate are applicable to the subject device.	Same
Performance Testing	The following non-clinical testing was performed on the Stryker Universal Select Sterilization Tray System: • Sterilization Validation • Dry Time Validation • Design Verification • Life Cycle Testing • Cleaning Validation • Biocompatibility	The following non-clinical testing was performed on the Stryker ChestShield Sterilization Tray System: • Sterilization Validation • Dry Time Validation The following non-clinical testing was leveraged from the predicate to support the performance of the subject device: • Design Verification • Life Cycle Testing • Cleaning Validation • Biocompatibility	Same

11. **Non-Clinical Performance Testing:** The following non-clinical testing was performed on the Stryker ChestShield Sterilization Tray System:

- **Sterilization and Dry Time Validation**

  Sterilization validations were performed to verify the effectiveness of steam sterilization of a fully loaded Stryker ChestShield Sterilization Tray System sterilized in a rigid sterilization container 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 132°C pre-vacuum steam autoclave half cycle exposures. Dry time was evaluated after sterilization. The Stryker ChestShield Sterilization Tray System was validated per ANSI/AAMI/ISO 17665-1:2006.

The subject device is identical in formulation and processing to the predicate device; therefore, the following non-clinical performance testing performed on the predicate Stryker Universal Select Sterilization Tray System is applicable to the subject Stryker ChestShield Sterilization Tray System:

- **Lifecycle Testing**
  Lifecycle testing was performed on the predicate device to verify that the tray system maintained functional quality requirements, material compatibility, and traceability after exposure to repeated pre-vacuum steam sterilization cycles and automated washing cycles and simulated functional use of the components.
- **Biocompatibility (ISO 10993-5)**
  Cytotoxicity testing was performed on the predicate device per ISO 10993-5 using the MEM Elution method. Test article extracts met the criteria of grade 2 or less cell lysis and reactivity, demonstrating the device is non-cytotoxic.

The following non-clinical testing was leveraged from the predicate device to support the performance of the subject device:

- **Design Verification**
  Design verification was performed on the predicate device to demonstrate the device complies with AAMI/ANSI ST77:2013 for handle strength testing. Additional design verification included containment verification during transport and simulated use, stacking verification and edge sharpness testing.
- **Cleaning Validation**
  Manual and automated cleaning validations were performed on the predicate device to validate the cleaning instructions using the worst case configured tray system per AAMI TIR 30:2011. The results met the acceptance criteria of residual protein of less than 6.4 µg/cm^2 and residual hemoglobin of less than 2.2 µg/cm^2, indicating that the recommended cleaning methods were effective in removing soil from all designated surfaces of the tray system that might be accessible to the end user.

12. **Conclusion:** Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject Stryker ChestShield Sterilization Tray System is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K173615.