



November 25, 2019

RP Medical, Inc.  
Jim Barley  
Director of RA/QA  
22715 Holyrood Avenue  
Maple Ridge, V2X 6E7 Ca

Re: K181845  
Trade/Device Name: Pivot System Sterilization case  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: KCT  
Dated: August 19, 2019  
Received: August 27, 2019

Dear Jim Barley:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth Claverie, M.S.  
Assistant Director for THT4B2  
Acting Assistant Director for THT4B1  
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

## Indications for Use

510(k) Number (if known)

K181845

Device Name

Pivot System Sterilization Case

### Indications for Use (Describe)

The RP Medical Pivot System Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Pivot System surgical instruments within a healthcare facility when used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap for use in healthcare facilities in order to maintain sterility of the enclosed devices. The Pivot System Sterilization Tray System has been validated for use in the following sterilization cycles:

|               |                                 |
|---------------|---------------------------------|
| Enclosure     | Pivot System Sterilization Case |
| Cycle         | Pre-Vacuum                      |
| Temperature   | 132°C (270°F)                   |
| Sterilization | Time 4 minutes                  |
| Pressure      | 2-15 PSIA                       |
| Minimum Dry   | Time 30 minutes in chamber      |

The maximum validated product loads for the trays in containers are as follows:

#### 2-Level Rack, Level 2, Pivot System Sterilization Tray

39.1960.01, RP OST Tool Handle, 3 each  
39.1960.02, RP OST Tool Rod, 3 each  
39.1960.51.01, RP OST Tool 1D RH 16mm, 1 each  
39.1960.51.02 RP OST Tool 1D RH 22mm, 1 each  
39.1960.20.01 RP OST Angle 162mm, 1 each  
39.1960.20.02 RP OST Angle 19mm, 1 each  
39.1960.20.03 RP OST Angle 21.5mm, 1 each  
39.1960.40.01 RP TM Spike Blade, 1 each  
39.1960.60.01 OST Reverse Blade 11mm, 1 each  
39.1960.60.02 OST Reverse Blade 16mm, 1 each  
39.1960.30.01 RP OST Tool Curve 16mm, 1 each  
39.1960.30.02 RP OST Tool Curve 19mm, 1 each  
39.1960.30.03 RP OST Tool Curve 21.5mm, 1 each  
39.1960.10.01 RP OST Straight 20mm, 1 each  
39.1960.10.02 RP OST Straight 40mm, 1 each  
39.1960.10.03 RP OST Straight 43mm, 1 each  
39.1960.10.04 RP OST Straight 47.5mm, 1 each  
39.1960.52.01, RP OST Tool 1D LH 16mm, 1 each  
39.1960.52.02 RP OST Tool 1D LH 22mm, 1 each

#### 2-Level Rack – Level 1, Pivot System Sterilization Tray

39.1960.01, RP OST Tool Handle, 1 each  
39.1960.02, RP OST Tool Rod, 1 each  
39.1960.05, Retractor, 1 each  
39.1960.07, RP OST System, 1 each  
39.1960.70.01 RP Curved Hip Long, 1 each  
39.1960.70.02 RP Curved Hip Short, 1 each  
39.1960.70.03 RP Curved Hip, 1 each

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

**510(k) Summary (As required by 21 CFR 807.92(a))**  
**K181845**

Date Prepared: November 22, 2019

**A. Applicant and Correspondent**

Applicant Name and Address: RP Medical, Inc.  
22715 Holyrood Avenue  
Maple Ridge, BC V2X 6E7 Canada

Contact Person: Ross Paul  
President

Phone: 604-418-4554

**Manufacturer** RP Medical, Inc.  
22715 Holyrood Avenue  
Maple Ridge, BC V2X 6E7 Canada

**B. Name of Device**

- Trade/Proprietary/Model Name: Pivot System Sterilization Tray System
- Common Name of Devices: Sterilization Tray
- Panel: General Hospital and Personal Use
- Classification Number: 21 CFR 880.6850
- Classification Name: Sterilization wrap
- Regulatory Class: II
- Product Code: KCT

**C. Predicate Device**

Device Name: Stryker Universal Select Sterilization Tray System  
Manufacturer: Paragon Medical  
Reference: K173615

**510(k) SUMMARY (Continued)****D. Device Description**

The RP Medical Pivot System Sterilization Tray System platform is designed to be compatible with the RP Medical Pivot Implant Extraction Osteotome surgical instruments. The Pivot System Sterilization Tray is constructed from thermoplastic plastics, aluminum and stainless steel. Each tray has evenly distributed steam holes.

Individuals instruments were designed to slide into 2 level storage racks. The racks have handles on the side to facilitate carrying. The Pivot System Sterilization Tray has a sliding latch mechanism to facilitate containment.

Each storage rack is set to a specific configuration and have stainless steel and silicone brackets and silkscreened artwork to assist the end user in correct placement of the instruments. The rack is designed to fit in a standard autoclave. The Pivot System Sterilization Tray System is reusable and provided in a non-sterile condition.

**E. Indications for Use**

The RP Medical Pivot System Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Pivot System surgical instruments within a healthcare facility when used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap for use in healthcare facilities in order to maintain sterility of the enclosed devices. The Pivot System Sterilization Tray System has been validated for use in the following sterilization cycles:

| Enclosure          | Pivot System Sterilization Tray |
|--------------------|---------------------------------|
|                    | Pre-Vacuum                      |
| Temperature        | 132°C (270°F)                   |
| Sterilization Time | 4 minutes                       |
| Pressure           | 2-15 PSIA                       |
| Minimum Dry Time   | 30 minutes in chamber           |

The maximum validated product loads for the trays in containers are as follows:

| Configuration                                                              | Maximum Validated Load Set Contents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>2-Level Rack,<br/>Level 2</b><br>Pivot System<br>Sterilization Tray     | <b>39.1960.01, RP OST Tool Handle, 3 each</b><br><b>39.1960.02, RP OST Tool Rod, 3 each</b><br><b>39.1960.51.01, RP OST Tool 1D RH 16mm, 1 each</b><br><b>39.1960.51.02 RP OST Tool 1D RH 22mm, 1 each</b><br><b>39.1960.20.01 RP OST Angle 162mm, 1 each</b><br><b>39.1960.20.02 RP OST Angle 19mm, 1 each</b><br><b>39.1960.20.03 RP OST Angle 21.5mm , 1 each</b><br><b>39.1960.40.01 RP TM Spike Blade, 1 each</b><br><b>39.1960.60.01 OST Reverse Blade 11mm, 1 each</b><br><b>39.1960.60.02 OST Reverse Blade 16mm, 1 each</b><br><b>39.1960.30.01 RP OST Tool Curve 16mm, 1 each</b><br><b>39.1960.30.02 RP OST Tool Curve 19mm, 1 each</b><br><b>39.1960.30.03 RP OST Tool Curve 21.5mm, 1 each</b><br><b>39.1960.10.01 RP OST Straight 20mm, 1 each</b><br><b>39.1960.10.02 RP OST Straight 40mm, 1 each</b><br><b>39.1960.10.03 RP OST Straight 43mm, 1 each</b><br><b>39.1960.10.04 RP OST Straight 47.5mm, 1 each</b><br><b>39.1960.52.01, RP OST Tool 1D LH 16mm, 1 each</b><br><b>39.1960.52.02 RP OST Tool 1D LH 22mm, 1 each</b> |
| <b>2-Level Rack –<br/>Level 1</b><br>Pivot System<br>Sterilization<br>Tray | <b>39.1960.01, RP OST Tool Handle, 1 each</b><br><b>39.1960.02, RP OST Tool Rod, 1 each</b><br><b>39.1960.05, Retractor, 1 each</b><br><b>39.1960.07, RP OST System, 1 each</b><br><b>39.1960.70.01 RP Curved Hip Long, 1 each</b><br><b>39.1960.70.02 RP Curved Hip Short, 1 each</b><br><b>39.1960.70.03 RP Curved Hip, 1 each</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

**F. Technological Characteristics:**

The following chart compares the technological characteristics of the subject and predicate devices:

|                             | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Comparison |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------|--|-----------|------------------------------|------------------------------|-------------|---------------|---------------|--------------------|-----------|-----------|------------------|------------|------------|-----------------------------|--------------------|--------------------|-----------|
| Device Name                 | Pivot System Sterilization Tray System                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Stryker Universal Select Sterilization Tray System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | N/A        |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| 510(k) Number               | K181845                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | K173615                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | N/A        |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Product Code                | KCT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | KCT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Same       |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Indications for Use         | <p>The RP Medical Pivot System Sterilization Tray System is intended to organize, enclose, sterilize, transport and store Pivot System surgical instruments within a healthcare facility when used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap for use in healthcare facilities in order to maintain sterility of the enclosed devices.. The Pivot System Sterilization Tray System has been validated for use in the following sterilization cycles:</p> | <p>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.</p> <p>The Stryker Universal Select Sterilization Tray System has been validated for use in the following sterilization cycles:</p> <table><tr><th></th><th colspan="2">Pre-Vacuum Steam</th></tr><tr><td>Enclosure</td><td>Rigid Container<sup>2</sup></td><td>Rigid Container<sup>2</sup></td></tr><tr><td>Temperature</td><td>132°C (270°F)</td><td>135°C (275°F)</td></tr><tr><td>Sterilization Time</td><td>4 minutes</td><td>3 minutes</td></tr><tr><td>Minimum Dry Time</td><td>30 minutes</td><td>30 minutes</td></tr><tr><td>Maximum Weight<sup>1</sup></td><td>25 lbs / 11.36 kgs</td><td>25 lbs / 11.36 kgs</td></tr></table> <p>Tray System has been validated in the following Aesculap SterilContainer cleared for pre-vacuum steam sterilization under K792558: Full DIN JK444 (base) and JK489 (lid) and ½ DIN JK346 (base) and JK389 (lid).</p> |            | Pre-Vacuum Steam |  | Enclosure | Rigid Container <sup>2</sup> | Rigid Container <sup>2</sup> | Temperature | 132°C (270°F) | 135°C (275°F) | Sterilization Time | 4 minutes | 3 minutes | Minimum Dry Time | 30 minutes | 30 minutes | Maximum Weight <sup>1</sup> | 25 lbs / 11.36 kgs | 25 lbs / 11.36 kgs | Different |
|                             | Pre-Vacuum Steam                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Enclosure                   | Rigid Container <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Rigid Container <sup>2</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Temperature                 | 132°C (270°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 135°C (275°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Sterilization Time          | 4 minutes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 3 minutes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Minimum Dry Time            | 30 minutes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 30 minutes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |
| Maximum Weight <sup>1</sup> | 25 lbs / 11.36 kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 25 lbs / 11.36 kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |            |                  |  |           |                              |                              |             |               |               |                    |           |           |                  |            |            |                             |                    |                    |           |



|                                    | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |        |                     |                |  | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Comparison |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------|----------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
|                                    | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Temp.  | Exposure Time (min) | Dry Time (min) |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |
|                                    | Pre-vacuum                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 132 °C | 4                   | 30             |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |
| Indications for Use<br>(continued) | The maximum validated product loads for the sterilization case are as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |        |                     |                |  | The maximum validated product loads for the tray system in containers are as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Different  |
|                                    | Configuration <sup>1</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |        |                     | Maximum        |  | Configuration <sup>1</sup> Maximum Validated Load Set Contents <sup>2,5</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |            |
|                                    | 2-Level Rack, Level 2<br>Rigid Sterilization Container <sup>3</sup><br>39.1960.01, RP OST Tool Handle<br>39.1960.02, RP OST Tool Rod<br>39.1960.51.01, RP OST Tool 1D RH 16mm<br>39.1960.51.02 RP OST Tool 1D RH 22mm<br>39.1960.20.01 RP OST Angle 162mm<br>39.1960.20.02 RP OST Angle 19mm<br>39.1960.20.03 RP OST Angle 21.5mm<br>39.1960.40.01 RP TM Spike Blade<br>39.1960.60.01 OST Reverse Blade 11mm<br>39.1960.60.02 OST Reverse Blade 16mm<br>39.1960.30.01 RP OST Tool Curve 16mm<br>39.1960.30.02 RP OST Tool Curve 19mm<br>39.1960.30.03 RP OST Tool Curve 21.5mm<br>39.1960.10.01 RP OST Straight 20mm<br>39.1960.10.02 RP OST Straight 40mm<br>39.1960.10.03 RP OST Straight 43mm<br>39.1960.10.04 RP OST Straight 47.5mm<br>39.1960.52.01, RP OST Tool 1D LH 16mm<br>39.1960.52.02 RP OST Tool 1D LH 22mm |        |                     |                |  | 29-12900 1.2 Upper-Face Plates/Screws Module with Lid (29-13941)<br>29-12901 1.2 Orbital Plates/Mesh Module with Lid (29-13941)<br>29-17900 1.7 Mid-Face Plates/Screws Module with Lid (29-13941)<br>29-17901 1.7 Mid-Face Plates Module with Lid (29-13941)<br><br>3-Level Rack –Qty.2 <sup>3</sup><br><br>29-17903 1.7 Orthognathic Plates Inlay<br>29-13901 Upper-/Mid-Face Instrument Tray with Lid (29-13921)<br>29-13920 ¼ DIN Instrument/Accessory Tray with Lid (29-13921)<br>29-23900 2.0/2.3 Mandible Screws Module with Lid (29- 13941)<br>29-23901 2.0/2.3 Mandible Plates Module with Lid (29- 13941)<br>29-23905 2.0/2.3 Mini Plates Inlay, Large<br>29-13904 Mandible Fracture Instrument Tray with Lid (29- 13921)<br>29-13905 Trocar Instrument |            |
|                                    | 2-Level Rack – Level 1<br>Rigid Sterilization Container <sup>4</sup><br>39.1960.01, RP OST Tool Handle<br>39.1960.02, RP OST Tool Rod<br>39.1960.05, Retractor<br>39.1960.07, RP OST System<br>39.1960.70.01 RP Curved Hip Long<br>39.1960.70.02 RP Curved Hip Short<br>39.1960.70.03 RP Curved Hip                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |        |                     |                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |
|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |        |                     |                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |
|--|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | <p>Tray with Lid (29-13921)</p> <p><b>29-23900</b> 2.0/2.3 Mandible Screws Module with Lid (29- 13941)</p> <p><b>29-23903</b> 2.0/2.3 Mandible Recon Plates Module with Lid (29-13941)</p> <p><b>3-Level Rack – Qty.1<sup>4</sup></b></p> <p><b>29-23904</b> 2.0/2.3 Mandible Recon Primary Plates Inlay</p> <p><b>29-13904</b> Mandible Fracture Instrument Tray with Lid (29-13921)</p> <p><b>29-13905</b> Trocar Instrument Tray with Lid (29- 3921)</p> <p><b>29-13920</b> ¼ DIN Instrument/Accessory Tray with Lid (29- 13921)</p> <p><sup>1</sup> Model numbers shown in table are Stryker® model numbers</p> <p><sup>2</sup> 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.)</p> <p><sup>3</sup> Tray system components part of the worst-case configuration in a full DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK446) and Lid (JK489) cleared under K792558</p> <p><sup>4</sup> Tray system components part of the worst-case configuration in a 1/2 DIN Rigid Sterilization Container validation in an Aesculap SterilContainer Base (JK346) and Lid (JK389) cleared under K792558</p> <p><sup>5</sup> No lumened devices were validated within the tray system as part of the product load. The Stryker Universal Select Sterilization Tray System does have any lumen claims.</p> |  |
|--|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

|                                                          |                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |
|----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| <b>Design</b>                                            | <p>The Pivot System Sterilization Tray platform is designed to be compatible with the Pivot system surgical instrumentation.</p> <p>Individual components were designed to slide in to 2-level storage racks. Racks have handles on the side to facilitate carrying. The tray lids have sliding latch mechanism to facilitate containment</p> | <p>The Stryker Universal Select Sterilization Tray System platform is designed to be compatible with Stryker implantable devices and surgical instrumentation.</p> <p>Individual components were designed to slide in to 2- and 3-level storage racks. Racks have handles on the side to facilitate carrying. Module and tray lids have sliding latch mechanism to facilitate containment.</p>                                                                                              | Similar           |
| <b>Materials of Construction</b>                         | Stainless Steel, Anodized Aluminum, Silicone and Thermoplastic Polymers                                                                                                                                                                                                                                                                       | Stainless Steel, Anodized Aluminum, Silicone, PPSU, Polypropylux                                                                                                                                                                                                                                                                                                                                                                                                                            | Similar           |
| <b>Configuration and Dimensions</b>                      | <p>Perforated 2-level and 3-level Racks that house the following tray components:</p> <p>Case - double      19.51" x 9.13" x 3.125"</p> <p>Outer</p> <p>Lid - Generic      20.00"x 9.60" x 0.437"</p> <p>Outer Lid</p>                                                                                                                        | <p>Perforated 2-level and 3-level Racks that house the following tray components:</p> <p>2-level Rack      9.80 x 9.70 x 5.27 inches</p> <p>3-level Rack      9.80 x 9.70 x 7.57 inches</p> <p>¼ DIN Instrument/Accessory      9.31 x 4.09 x 1.54 inches Tray</p> <p>¼ DIN Instrument/Accessory      9.29 x 4.30 x 0.51 inches Tray Lid</p> <p>½ DIN Instrument/Accessory      9.31 x 8.55 x 1.54 inches Tray</p> <p>½ DIN Instrument/Accessory      9.29 x 8.71 x 0.55 inches Tray Lid</p> | Different         |
|                                                          | <b>Subject Device</b>                                                                                                                                                                                                                                                                                                                         | <b>Predicate Device</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Comparison</b> |
| <b>Material Compatibility with Sterilization Process</b> | Performance testing demonstrated that the materials of construction are compatible with repeated steam sterilization cycles.                                                                                                                                                                                                                  | Performance testing demonstrated that the materials of construction are compatible with repeated steam sterilization cycles.                                                                                                                                                                                                                                                                                                                                                                | Same              |

|                                       | Subject Device                                    |                |          | Predicate Device                                  |                |          | Comparison |
|---------------------------------------|---------------------------------------------------|----------------|----------|---------------------------------------------------|----------------|----------|------------|
| Sterilization Parameters (Pre-Vacuum) |                                                   |                |          |                                                   |                |          | Different  |
|                                       | Cycle                                             | Temp           | Exposure | Cycle                                             | Temp           | Exposure |            |
|                                       |                                                   |                |          | Pre-Vacuum                                        | 132° C (270°F) | 4 Min    |            |
|                                       |                                                   |                |          |                                                   | 135°C (275°F)  | 4 Min    |            |
|                                       |                                                   |                |          |                                                   |                |          |            |
|                                       | Pre-Vacuum                                        | 132° C (270°F) | 4 Min    |                                                   |                |          |            |
| Perforation                           | Evenly distributed perforated steam hole pattern. |                |          | Evenly distributed perforated steam hole pattern. |                |          | Similar    |
| Sterilization Method                  | Pre-vacuum                                        |                |          | Pre-vacuum                                        |                |          | Same       |
| Reusable                              | Yes                                               |                |          | Yes                                               |                |          | Same       |
| Patient Contact                       | No direct patient contact                         |                |          | No direct patient contact                         |                |          | Same       |
| Air Permeance                         | Yes                                               |                |          | Yes                                               |                |          | Same       |

### G. Summary of Non-clinical Testing

Shown below is a listing of the non-clinical test that was performed to verify that the subject device met the standards recommendation.

| Name of the Test Method                                                        | Purpose                                                                                   | Acceptance Criteria                                                                        | Results                                                                                 |
|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Agar Overlay Method per ISO 10993-5                                            | To evaluate an extract of the test article for cytotoxicity to mammalian cells in culture | Test articles scoring 0, 1 or 2 will be considered 'non-cytotoxic'                         | The test article scored 0 at 24, 48 and 72 +/- 4 hours and is considered non-cytotoxic. |
| AAMI ST77:2013, Containment Devices for Reusable Medical Device Sterilization. | Handle Weight Capacity Test for the Sterilization Case                                    | No visible deformation, cracking or other evidence of damage on the Handles after testing. | There was no visible deformation, cracking or other evidence of damage on the           |

|  |                                                |                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                     |
|--|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                                                |                                                                                                                                                                               | Handles after testing.                                                                                                                                                                                                                                                                                                                                                                              |
|  | Reliability testing for the Sterilization Case | No significant wear after 100 sterilization cycles. Significant wear is defined as extreme discoloration, peeling and/or cracking of any component of the sterilization tray. | A side by side comparison of a new vs the Sterilization Case sterilized 102 times. There was a slight yellowing of the case color and the white print within the Sterilization Case. The discoloration was minimum and none of the printing was erased or faded so that it could not be read. In addition, there was no peeling and/or cracking of any of the components of the sterilization case. |

The Pivot System Sterilization Tray met the appropriate requirements contained in the following standards:

1. AAMI ST77:2013, Containment devices for reusable medical device sterilization
2. AAMI TIR 30, A compendium of processes, materials, test methods, and acceptable criteria for cleaning reusable medical devices
3. ANSI/AAMI/ISO 17665-1, Sterilization of health care products-Moist heat- Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices
4. ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
5. ANSI AAMI ISO 14971:2007/(R)2010, Medical Devices – Application of Risk Management to Medical Devices

## H. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the RP Medical Pivot System Sterilization Tray System is as safe, as effective, and performs as well as or better than the legally marketed predicate, Stryker Universal Select Sterilization Tray System, cleared under K173615, Class II (21 CFR 880.6850, product code KCT).