DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 9, 2016

Jewel Precision Sheet Metal and Machine, Inc.
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K162600
Trade/Device Name: Jewel Precision Reusable Rigid Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 2, 2016
Received: December 5, 2016

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162600

Device Name
Jewel Precision Reusable Rigid Sterilization Container System

Indications for Use *(Describe)*

The Jewel Precision Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used, for a maximum of 30 days.

Jewel Precision Reusable Rigid Sterilization Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization at 270°F (132°C) for 4 minutes with a drying time of 30 minutes.

Reusable containers, covers, filter holders, insert trays, and accessory items such as brackets of various configuration, dividers, caddies, and silicone nipple mats are intended to organize and secure the enclosed medical devices during sterilization and storage of the container.

Filter media allows ingress and egress of sterilant gas while providing a microbial barrier. Filter media is single use only.

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
PRAStaff@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."

K162600 510(k)

Summary

per 21 CFR 807.92

Submitter Information	
Name	Jewel Precision Sheet Metal and Machine, Inc.
Address	200 Commerce Road Cedar Grove, NJ 07009
Phone Number	973-857-5545
Fax Number	973-857-5548
Establishment Registration Number	3004112448
Name of Contact Person	Gary Schneberger, Manager Quality Assurance & Regulatory Affairs
Date Prepared	9-December-2016
Device Information	
Trade or Proprietary Name	Jewel Precision Reusable Rigid Sterilization Container System
Common or Usual Name	Sterilization Container
Classification Name	Sterilization Wrap, Containers, Trays, Cassettes, and Other Accessories
Classification Panel	80
Regulation	Class II per 21CFR 880.6850
Product Code(s)	KCT
Legally Marketed Device to which equivalence is claimed	Genesis Reusable Rigid Sterilization Container System K142529
Reason for 510(k) submission	To obtain clearance to market for a new medical device
Device Description	The Jewel Precision Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used, for a maximum of 30 days. The containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used as described in the instructions for use. Reusable trays and accessory items such as brackets of various configuration, dividers, caddies, and silicone nipple mats are intended to organize and secure the enclosed medical devices during sterilization and storage of the container. The Jewel Precision Reusable Rigid Sterilization Container System comprises a sealed sterilization container consisting of a base, cover, filter retainers, single use replaceable paper filters, and accessories consisting of inner trays, and support brackets. Support brackets are configured to securely support container contents, and are secured to inner trays with stainless steel screws and cap nuts. The container is designed to allow efficient exposure of the tray's contents to sterilant gas during the sterilization process, and to contain and protect reusable surgical instruments during sterilization, transport, and storage. The cover incorporates a sealing gasket, and is secured to the base with latches which lock in place. The latching mechanism places a load on the gasket, which is held in compression against the top surface of the container base, maintaining sterile integrity and preventing unwanted separation. The cover also incorporates an alignment flange along its perimeter, which ensures correct alignment of the cover with the container bottom. Provisions are made on the external container surfaces for the use of user provided Sterilizer Load Data Cards and user provided Tamper Evident Locks, through the incorporation of stainless steel Load Data Card Holders, and stainless steel hasp and pin style Container Locks which accommodate Tamper Evident Locks. The containers

	are designed to fit standard autoclaves, and are manufactured of materials capable of withstanding repeated steam sterilization cycles. The containers and accessories are manufactured from materials which are suitable for use with Pulsed Pre-Vacuum Steam Sterilization methods. Filter media is Ahlstrom Reliance 335 WL11359D paper, FDA cleared under K800123, which allows ingress and egress of sterilant gas while providing a microbial barrier. The Filter media is single use only. The Jewel Precision Reusable Rigid Sterilization Container System is used to organize, protect, and transport surgical instruments during steam sterilization and subsequent storage. The Jewel Precision Reusable Rigid Sterilization Container System maintains sterility of enclosed instruments, having been validated for a period of 30 days post sterilization, using containers previously subjected to more than 100 sterilization usage cycles. The Jewel Precision Reusable Rigid Sterilization Container System is intended for sterilization of non-porous and porous items, e.g. scissors, hooks, probes, extractors, suction instruments, drivers, rasps, obturators, etc. The container does not come into direct patient contact while in use.

The containers, insert trays, covers, brackets, and filters are manufactured from the following materials:

Material	Specification
Aluminum Sheet Metal	Alloy 5052 H32
Aluminum Bar Stock	Alloy 6061
Stainless Steel Sheet Metal	SAE 304
Stainless Steel Rod Stock	AISI 303
Nylon Powder Coating	USP Class VI Polyamide 11
Silicone Elastomer	USP Class VI Vinyl Methyl Siloxane, Platinum Cured
Filter Paper	Ahlstrom Reliance 335 WL11395D, a Wet Laid Non-Woven Fabric comprised of Natural Wood Pulp Fibers bonded with a Synthetic Resin Binder, having a Basis Weight of 52.2 g/m². Cleared by FDA for use as a Sterilization Barrier System under 510(k) Number **K800123**.

Indications For Use

The Jewel Precision Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used, for a maximum of 30 days.

Jewel Precision Reusable Rigid Sterilization Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization at 270 °F (132 °C) for 4 minutes with a drying time of 30 minutes.

Reusable containers, covers, filter holders, insert trays, and accessory items such as brackets of various configuration, dividers, caddies, and silicone nipple mats are intended to organize and secure the enclosed medical devices during sterilization and storage of the container.

Filter media allows ingress and egress of sterilant gas while providing a microbial barrier. Filter media is single use only.

Summary of the Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	**Predicate Device - K142529**	**New Device**
Intended Use	The Genesis Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used for a maximum of 180 days. Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization, immediate use pre-vacuum steam sterilization and 100% ethylene oxide sterilization when used as described in the instructions for use. Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices during sterilization and storage of the container. Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter.	The Jewel Precision Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used, for a maximum of 30 days. Jewel Precision Reusable Rigid Sterilization Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used as described in the instructions for use. Reusable containers, covers, filter holders, insert trays, and accessory items such as brackets of various configuration, dividers, caddies, and silicone nipple mats are intended to organize and secure the enclosed medical devices during sterilization and storage of the container. Filter media allows ingress and egress of sterilant gas while providing a microbial barrier. Filter media is single use only.

	Data cards, filters and tamper evident arrows are single use only.	
Container	Anodized 5000 and 1100 series aluminum; 300 series stainless steel	Same
Gasket	Closed cell silicone foam	USP Class VI silicone elastomer
Filter	SMS polypropylene for all sterilization modalities	Ahlstrom Reliance 335 WL11395D, a Wet Laid Non-Woven Fabric comprised of Natural Wood Pulp Fibers bonded with a Synthetic Resin Binder, having a Basis Weight of 52.2 g/m². Substantially equivalent to Dextex II Grade 3592 cleared by FDA for use as a Sterilization Barrier System under 510(k) Number **K800123** for dynamic air removal (pre-vacuum) steam sterilization.
Trays (Baskets)	304 Stainless Steel, electropolished	1100 and 5000 series anodized aluminum; nylon coated 1100 and 5000 series aluminum
Dividers, Brackets	5000 series aluminum	Nylon coated 1100 and 5000 series aluminum with silicone elastomer inserts
Clips, Posts, Pins	300 and 400 series stainless steel	Same
Silicone Bars, Mats	Silicone elastomer	Same
Material Compatibility	Intrinsically stable metals, composites, thermoplastic and thermosetting polymers designated for constant use at temperatures above 135°C	Intrinsically stable metals, thermoplastic and thermosetting polymers designated for constant use at temperatures above 135°C
Volume to Vent Ratio	24.0 to 182.3 in^3 / in^2	JP-24-6: 76.55 in^3 / in^2 The volume to vent ratio of the new device falls within the ratios cited for the predicate device.
Container Dimensions	9.5" x 12.4" x 3.8" to 23.1" x 12.5" x 8.8"	23" x 11.2" x 7"
Microbial Barrier Properties / Shelf Life	Maintains sterility of the enclosed medical device until used for a maximum of 180 days.	Maintains sterility of the enclosed medical device until used for a maximum of 30 days.
Sterilization parameters for Pre-Vacuum steam for Lumen devices	Lumens: 2.68 mm (ID) x 450 mm (L) – Qty 16 Lumens: 1.37 mm (ID) x 242 mm (L) – Qty 10 Total: 26	<u>Lumens:</u> <u>Quantity</u> 0.130" x 13 1/8" 3 0.155" x 13 1/4" 1 0.150" x 12 1/4" 1 0.048" x 6" 1 0.064" x 6" 1 0.055" x 7 1/2" 1 0.066" x 7 1/2" 1 0.073" x 7 1/2" 1 0.092" x 7 1/2" 1 0.106" x 7 1/2" 1 0.110" x 7 1/2" 1 0.115" x 7 1/2" 1 0.075" x 9 5/8" 6 0.230" x 7 1/4" 6 0.095" x 4" 1 0.098" x 5 3/4" 1 Total: 28

While the indication statements for the Jewel Precision Reusable Rigid Sterilization Container System differ from those for the predicate device, the differences are not critical to the intended use of the device in that the subject device has been demonstrated both to perform as intended allowing sterilization of the enclosed medical device, and maintain sterility of the enclosed device until used, for a maximum of 30 days.		
Performance Data		
Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary – New Device		
Characteristic	**Standard / Test / FDA Guidance**	**Results Summary**
Sterilization Efficacy: Pre-Vacuum Steam	ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10^{-6} using biological (BI) overkill method
Dry Time for Dynamic Air Removal (Pre-Vacuum Steam Modality)	ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated a validated method of drying by absence of visible moisture
Biocompatibility Testing of the following materials after 100 cycles of cleaning and steam sterilization:	ISO 10993-5:2009/(R) 2014 Biological evaluation of medical devices-Part 5: Tests for *in vitro* cytotoxicity	
Filter Media		Pass
USP Class VI Silicone Cover Gasket with UAP Class VI Silicone Adhesive		Pass
Anodized 5052 H32 Aluminum (Container and Cover)		Pass
USP Class VI Silicone Filter Retainer Gasket with USP Class VI Silicone Adhesive		Pass
Filter Retainer Cover, 304 Stainless Steel		Pass
Container Handle, 303 Stainless Steel		Pass
USP Class VI Silicone Bracket Insert		Pass
USP Class VI Nylon (Polyamide 11) Coated Bracket		Pass
Anodized 5052 H32 Aluminum (Insert Tray)		Pass
Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and / or Clinical Information		
Not Applicable – No clinical tests were conducted for this submission.		

Conclusions Drawn from Non-Clinical and Clinical Data

The Jewel Precision Reusable Rigid Sterilization Container System has been validated to meet the established performance criteria. The results of the verification studies demonstrate that the sterilization containers perform as intended, and based on the non-clinical tests performed the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K14529, Class II (21 CFR 880.6850), Product Code KCT, identified on page 1 of this section.