K131455

510(k) SUMMARY

Submitter Name:	Restore Medical Solutions, Inc.
Submitter Address:	100 Peabody PL STE 150 P.O. Box 3118 Memphis, TN 38103
Contact Person:	Shawn M. Flynn, President
Phone Number:	404-805-8305
Fax:	636-680-3644
Date Prepared:	May 20, 2013

AUG 30 2013

Device Trade Name:	Restore™ Modular Sterilization Tray System
Classification Name:	Sterilization Wrap Containers, Cassettes, and Accessories
Classification Class and Regulation Number:	Class II 21 CFR 880.6850
Product Code:	KCT
Predicate Device(s):	K012105, PolyVac Inc., PolyVac Surgical Instrument Delivery System K040223, Symmetry Medical Inc., PolyVac Surgical Instrument Delivery System
Statement of Intended Use:	The Restore™ Modular Sterilization Tray System is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses when used in conjunction with a FDA cleared sterilization wrap. The Modular Sterilization Tray System may be used with common surgical instruments such as hammers, rasps, drivers, chisels, ringed-handled instruments, rongeurs, pickups, including but not limited to short-lumened devices etc. The validated total weight for tray and contents was 20 pounds.

Reusable Medical Device Challenge Conditions		
Minimum Inner Diameter	Maximum Length	Number of lumens
1.8 mm	4 inches	2

High Vacuum (pre-vacuum, three pulse, standard):
Temp: 270° F
Exposure Time: 4 Minutes
Cycle Dry Time (wrapped): 20 Minutes (minimum)
Cool Time: Varies according to load contents

NOTE: Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.

Device Description:	The Restore™ Modular Sterilization Tray System is designed using materials that can be reused with steam sterilization methods. The Restore™ system has an even distribution of holes in relation to its size for optimal steam penetration. The basic system includes either a 10 x 20 x 4 inch or 10 x 10 x 4 inch aluminum tray with lids and a variety of insert tray assemblies and lids. The central function is an adjustable racking and multi-functioning stringer device, which is designed for the organization and alignment of surgical instruments for pre-sterilization cleaning decontamination, and sterilization cycles of surgical devices in healthcare facilities. For the sterilization process, the tray system may be either wrapped in FDA-cleared sterilization wrap designed for this purpose or placed in a rigid container.
Summary of Testing:	Cleaning and Sterilization Validation testing was performed by under GLP conditions by a contract test laboratory according to AAMI TIR30:2011 and AAMI TIR12:2010 standards. The testing validated the parameters for vacuum settings, temperature, exposure time, cycle dry time wrapped and in a sterilization container, and cool time.
Comparison to the Predicate Devices:	The Restore™ Modular Sterilization Tray System was compared to the predicate devices by review of intended use and technological characteristics - product design, device characteristics and materials. Please refer to the *Comparison Table for Substantial Equivalence* on pages 3 and 4 for the comparison parameters.
Substantial Equivalence Discussion:	The Restore tray system was found to be substantially equivalent based on the same intended use and the side-by-side comparison of the technological characteristics. The additional Stringer feature offered by the Restore™ Modular Sterilization Tray System does not impact the intended use in comparison to the predicate devices. Further the validation testing of the loaded Restore tray system assures the device is safe and effective for its intended use.
Verifications regarding this 510(k) Summary:	The summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information
Substantial Equivalence Conclusion:	It is concluded that the Restore™ Modular Sterilization Tray System is substantially equivalent, based on the nonclinical testing (discussed above) that demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device.

Comparison Table for Substantial Equivalence

<table>
<tr><th></th><th>Proposed Device</th><th>Predicates</th></tr>
<tr><td>Product Name
510(k) Number</td><td>Restore™ Modular Sterilization Tray System</td><td>PolyVac Surgical Instrument Delivery System
K040223, K012105</td></tr>
<tr><td>Product Code,
Regulation #,
Name</td><td>KCT
21 CFR 880.6850
Sterilization Wrap Containers, Trays, Cassettes & Other Accessories</td><td>KCT
21 CFR 880.6850
Sterilization Wrap Containers, Trays, Cassettes & Other Accessories</td></tr>
<tr><td>Manufacturer</td><td>Restore Medical Solutions, Inc.</td><td>Symmetry Medical, Inc. (Previously PolyVac, Inc for K012105)</td></tr>
<tr><td>Indications for Use Statement:</td><td>The Restore™ Modular Sterilization Tray System is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses when used in conjunction with a FDA cleared sterilization wrap.

The Modular Sterilization Tray System may be used with common surgical instruments such as hammers, rasps, drivers, chisels, ringed-handled instruments, rongeurs, pickups, including but not limited to short-lumened devices etc. The validated total weight for tray and contents was 20 pounds.

Reusable Medical Device Challenge Conditions
Minimum Inner Diameter: 1.8 mm
Maximum Length: 4 inches
Number of lumens: 2

High Vacuum (pre-vacuum, three pulse, standard):
Temp: 270° F
Exposure Time: 4 Minutes
Cycle Dry Time (wrapped): 20 Minutes (minimum)
Cool Time: Varies according to load contents

NOTE: Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.</td><td>The PolyVac's delivery systems consist of perforated trays with lids, which are intended to enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical devices is maintained until used.

PolyVac's delivery systems are to be sterilized in one of the following cycles:
Prevacuum Steam: 132°C - 4 minutes minimum
Gravity Stream: 132°C - 30 minutes minimum
Gravity Stream: 121°C - 55 minutes minimum

Sterilization Method: Ethylene Oxide (for K040223)</td></tr>
</table>

(table continues to next page)

Device Description: Design, Components, Configurations, Dimensions	• Base trays (10 x 20 x 4 & 10 x 10 x 4 inches) • Modular insert trays and lids. • Evenly distributed perforated hole pattern. • Silicone Dividers • In-situ Racking Device/Stringer	• Base tray (17.3 x 7.25 x 4 inches) • Modular insert trays and lids. • Evenly distributed perforated hole pattern. • Silicone mats
Material Composition	Trays & Lids: Aluminum, 300 Series stainless steel, biomedical grade silicone Stringer: Ultem*HU1004 Resin	Trays & Lids: Aluminum, 300 Series stainless steel, biomedical grade silicone; or Radal® R Plastic
Sterilant penetration	Each tray and lid contains evenly distributed hole pattern in relation to its size.	Each trays and lids contains evenly distributed hole pattern in relation to its size.
Pre-Vac Steam Sterilization Validation Parameters	High Vacuum (pre-vacuum, three pulse, standard): Temp: 270°F Exposure Time: 4 Minutes Cycle Dry Time: 15 Minutes (minimum) Cool Time: Varies according to load contents	Prevacuum Steam: 132°C - 4 minutes minimum Gravity Stream: 132°C - 30 minutes minimum Gravity Stream: 121°C - 55 minutes minimum
Reusable	Yes	Yes
Material Compatibility with sterilization process	Yes	Yes
ISO 10993 Biocompatibie	Yes	Yes

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

August 30, 2013

Restore Medical Solutions, Incorporated
C/O Ms. Patsy J. Trisler
President Consultant
Trisler Consulting
5600 Wisconsin Ave. #509
CHEVY CHASE Maryland 20815

Re: K131455
Trade/Device Name: Restore™ Modular Sterilization Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: July 24, 2013
Received: July 26, 2013

Dear Ms. Trisler:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

For Kwame Ulmer

Lester W. Schultheis Jr

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): **K131455**

Device Name: **Restore™ Modular Sterilization Tray System**

Indications for Use:

The Restore™ Modular Sterilization Tray System is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses when used in conjunction with a FDA cleared sterilization wrap.

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Sreekanth Gutala -S
2013.08.29 14:43:28 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131455