OCT 2 2 2004

K040223

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Symmetry Medical Inc.
220 West Market Street
Warsaw, Indiana 46582

2. Contact: D. Darin Martin
Symmetry Medical Inc.
220 West Market Street
Warsaw, Indiana 46582

3. Product: PolyVac Surgical Instrument Delivery System
880.6850 Sterilization Wrap
Class II
Pack, Sterilization Wrapper, Bag and Accessories
80 KCT

4. Common Names:

Minitainer	Modultainer IV
Instrument Cassettes	Opitainer
Standard Modultainer	Universal
Modultainer II	Modultainer III
Modultainer II Hybrid	Vault
LapCare /Arthrocare	

Description:

PolyVac Delivery Systems consist of different sizes of the same basic configuration. All systems consist of a minimum of a plastic or metal base and lid. All lids can be fastened to the base by means of assembled hardware or by a locking tab, designed as part of the lid. Accessories may be used with systems to organize or separate contents to be placed in them for use.

The Delivery Systems are designed using plastic and metal materials that can be reused with steam or Ethylene Oxide sterilization methods. Each tray and lid has an evenly distributed hole pattern in relation to its size.

Intended Use:

PolyVac's delivery systems are intended to 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,

PolyVac's delivery systems are to be sterilized in one of the following cycles:

Prevacuum Steam : 132°C - 4 minutes minimum
Dry for 20 – 40 minutes as needed

Gravity Steam: 132°C - 30 minutes minimum
Gravity Steam: 121°C - 55 minutes minimum
Dry for 20 – 50 minutes as needed

Ethylene Oxide

Technological Characteristics:

The PolyVac Delivery System does not incorporate any new technological characteristics or material as compared to legally marketed devices.

Performance Data:

A summary of the following testing is provided to support the premarket notification for the new Ethylene Oxide indication:

Ethylene Oxide Qualification: The test articles were inoculated with spore strips and biological indicator organisms, and chemical indicators were placed. They were then wrapped in a double layer of approved sterilization wrap and placed into the ethylene oxide sterilizer for processing. The system was successfully sterilized in a 60 minute ETO half cycle. The sterilization tests demonstrate a six log reduction capability of all spores strips and inoculated devices.

Ethylene Oxide Residual Evaluation: Radel-R materials were exposed to full Ethylene Oxide Cycles and aerated for 11 hr. and 35 min. Residual concentrations of EO, ECH, and EGly, were all within acceptable limits.

Substantial Equivalence:

The Delivery Systems offered by PolyVac are of the same design as sterilization cases and trays manufactured by PolyVac under a previously cleared 510(k) – K012105. The devices are substantially equivalent to other sterilization cases cleared for use with Ethylene Oxide: Aptimax – K013003, Advanced Sterilization Products, and Metapak – K993535, Riley Medical, Inc.

Conclusions:

The studies conducted on PolyVac's Delivery Systems demonstrate that the device is substantially equivalent to other sterilization cases and trays currently in commercial distribution. Additionally, it provides a reliable means of packaging, transporting, and storing instruments for sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

Symmetry Medical, Incorporated
C/O Mr. David C. Furr
Official Correspondent
FDC Services
7822 Ladue Glen
Fort Wayne, Indiana 46804

Re: K040223
Trade/Device Name: Poly Vac Surgical Instrument Delivery System
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: August 5, 2004
Received: August 6, 2004

Dear Mr. Furr:

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.

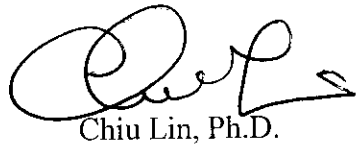
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K040223

Device Name: PolyVac Surgical Instrument Delivery System

Intended Use: 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 sterilant penetration and air removal, When used in conjunction with an approved sterilization wrap.

Sterilization Method: Ethylene Oxide

Prescription Use ___ or Over-the-counter use X
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janette Y. Michaud M.D.
FOR DR. CHIU LIN

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

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