K071783

SEP 0 9 2008

510(k) SUMMARY
(PURSUANT TO 21 CFR 807.92)

Submitted by: ContainMed, Inc.
1404 Main St.
Speedway, IN 46224
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Submission Date: 6/29/2007

Contact Person: Todd E. Bettenhausen, Vice-President
tbettenhausen@containmed.com

Trade Name: VersaPod™ Instrument Trays
Common Name: Sterilization Trays
Device Class: II
Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (CFR 880.6850, Product Code KCT)

Predicate Device: K012105—Poly Vac Surgical Instrument Delivery System

Device Description:

ContainMed VersaPod™ Instrument Trays consist of an anodized aluminum base with handles and latches and an anodized aluminum cover. Bases have the following external dimensions: 510mm (length) x 250mm (width) x 40mm, 60mm, or 82mm (depth). An optional anodized aluminum insert tray is available for use with the 82mm deep base only. Bases, covers, and insert trays are highly perforated to facilitate steam sterilant penetration. Anodized aluminum placard, and silicone rubber mat and instrument holding accessories (with stainless steel mounting hardware), are available to identify, organize, and protect the contents during use.

Intended Use:

ContainMed, Inc. VersaPod™ Instrument Trays organize, protect, and transport medical instruments during prevacuum steam sterilization and subsequent storage. They do not maintain sterility unless used in conjunction with an FDA-cleared and legally marketed sterilization wrap. This device has not been validated for sterilization of instruments that are porous or have lumens.

Prevacuum Steam Cycle Parameters: 132° C, 4 minutes
Drying: 45 minutes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

Mr. Todd E. Bettenhausen
Vice-President
ContainMed, Incorporated
1404 Main Street
Speedway, Indiana 46224

Re: K071783
Trade/Device Name: ContainMed, Inc. VersaPod™ Instrument Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: August 15, 2008
Received: August 18, 2008

Dear Mr. Bettenhausen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K071783

Device Name: ContainMed, Inc. VersaPod™ Instrument Trays

Indications for Use:

ContainMed, Inc. VersaPod™ Instrument Trays organize, protect, and transport medical instruments during prevacuum steam sterilization and subsequent storage. They do not maintain sterility unless used in conjunction with an FDA-cleared and legally marketed sterilization wrap. This device has not been validated for sterilization of instruments that are porous or have lumens.

Prevacuum Steam Cycle Parameters:	132° C, 4 minutes Drying: 45 minutes

VersaPod™ System Components and Accessories

CAT. NO.	DESCRIPTION
VP-BC40	Base w/Cover, 40mm
VP-BC60	Base w/Cover, 60mm
VP-BC82	Base w/Cover, 82mm
VP-BCT82	Base w/Insert Tray/Cover, 82mm
VP-H20	Instrument Holder, 20mm
VP-H20S	Instrument Holder, 20mm w/Stop
VP-H30	Instrument Holder, 30mm
VP-H30S	Instrument Holder, 30mm w/Stop
VP-H40	Instrument Holder, 40mm
VP-H40S	Instrument Holder, 40mm w/Stop
VP-S40	Instrument Holding Strip, 40mm
VP-M15	Mat, 15mm
VP-PXX	Placard

Note: All accessories include mounting hardware.

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

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shula R Murphy MD

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

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