

K080645

510(k) Summary

Trade Name: Primo Port

MAY - 2 2008

Sponsor: STD Med, Inc.
75 Mill Street
Stoughton, MA 02072
FDA Registration No. 1222928

Device Common Name: Subcutaneous Port & Catheter

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Device: K0570911 – STD Med Primo Port

Product Description:

The device described in this 510(k) consists of a a modified sterile, single use, implantable port, with catheter and catheter locks. The port is introduced into the vascular system and attached to the port stem using a catheter lock. The port is then sutured under the skin in the area of the subclavian fossa. The port is accessed percutaneously usina a non-coring needle that penetrates a silicone rubber septum at the top of the port. The port system is the mechanism with which fluids can pass into and out of the central venous system.

Indications for Use:

The STD Med Primo Port is a totally-implantable vascular access device designed to provide long term, repeated access to the vascular system.

Safety and Performance:

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), STD Med has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. A description and summary of the verificaion and validation testing methods and results utilized to qualify the device modifications is included in this submission.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate device, the proposed modified STD Med, Inc. Primo Port has been shown to be safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

STD Med, Incorporated
C/O Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

MAY - 2 2008

Re: K080645

Trade/Device Name: STD Med Primo Port Poly
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: April 18, 2008
Received: April 21, 2008

Dear Ms. Papineau:

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

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

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510(k) Number (if known): K080645

Device Name: STD Med Primo Port Poly

Indications for Use:

The STD Med Primo Port Poly is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

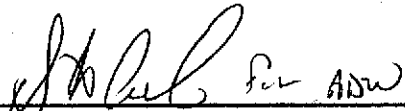
Prescription Use x
(Per 21 CFR 801 Subpart D)

OR

Over-the -Counter Use _____
(Per 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)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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