SEP - 9 2003

K032557

6 510(K) SUMMARY [AS REQUIRED BY 21 CFR 807.92(C)]

Submitter's Name / Contact Person

Manufacturer
Horizon Medical Products, Inc.
One Horizon Way
Manchester, Georgia 31816

Contact
Scott Moeller
Director of Quality Assurance and Regulatory Affairs

General Information

Trade Name	Triumph™ VTX® Port with LifeValve® Catheter
Common Name	Vascular access port with intravascular catheter
Classification Name	Subcutaneous, implanted, intravascular infusion port and catheter Classification Number: 21 CFR §880.5965 Classification Panel: General Hospital Product Code: LJT
Equivalent Devices	**Product; Manufacturer; 510(k) #** • Triumph-1® Port Systems; Horizon Medical Products; K933986, K951814 • Vortex® Access Systems; Horizon Medical Products; K010189 • LifeValve® Central Venous Catheter; Horizon Medical Products; K031718

Device Description

The Triumph™ VTX® Port with LifeValve® Catheter is a device comprised of a vascular access port and a catheter. The Triumph™ VTX® Port is available in a titanium or polysulfone configuration with a self sealing silicone rubber septum designed to maintain integrity after repeated punctures with an anti-coring needle. The LifeValve® Catheter incorporates a bidirectional valve assembly at the distal tip. The catheter is equipped with a pre-threaded stiffening stylet to facilitate passage of the catheter through the introducer. The positioned LifeValve® Catheter is secured to the Triumph™ VTX® Port reservoir with a locking mechanism. The products are packaged in a sterile tray with an introducer kit and components.

Intended Use

The Triumph™ VTX® Port with LifeValve® Catheter is a totally implantable vascular access system intended for the delivery of medications, intravenous fluids, parenteral nutrition solutions or blood products. The Triumph™ VTX® Port with LifeValve® Catheter is also indicated for the withdrawal of blood samples.

Substantial Equivalence Comparison

The Triumph™ VTX® Port with LifeValve® Catheter is substantially equivalent to the Horizon Medical Products, Inc. (HMP) Triumph-1® Port System, Vortex® Access System and LifeValve® Central Venous Catheter.

The subject and predicate devices are substantially equivalent in intended use and fundamental scientific technology. The Triumph™ VTX® Port and the Triumph-1® and Vortex® Access System predicates are substantially similar in configuration, dimensions, and materials. The LifeValve® Catheter is essentially identical to the previously cleared LifeValve® Catheter. The Triumph™ VTX® Port with LifeValve® Catheter design was evaluated through Horizon Medicals risk analysis and qualified through design verification testing following established Design Control procedures. No new questions of safety or effectiveness for implantable ports or central venous catheters were raised by the risk analysis or testing of the Triumph™ VTX® Port with LifeValve® Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Mr. Scott Moeller
Director of Quality Assurance and Regulatory Affairs
Horizon Medical Products, Incorporated
1 Horizon Way
Manchester, Georgia 31816

Re: K032557
Trade/Device Name: Triumph™ VTX® Port with life Valve® Catheter
Regulation Number: 21CFR 880.5965
Regulation Name: Subcutaneous, Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: August 18, 2003
Received: August 19, 2003

Dear Mr. Moeller:

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 (301) 594-4618. 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,

Susan Runner, DDS, MA
Interim 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 (if known): _____

Device Name: **Triumph™ VTX® Port with LifeValve® Catheter**

Indications for Use:

The Triumph™ VTX® Port with LifeValve Catheter is a totally implantable vascular access system intended for the delivery of medications, intravenous fluids, parenteral nutrition solutions or blood products. The Triumph™ VTX® Port with LifeValve® Catheter is also indicated for the withdrawal of blood samples.

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

510(k) Number: K032557

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

Concurrence of CDRH, Office of Device Evaluation (ODE)