

EXHIBIT F

SAFETY AND EFFECTIVENESS

Product Description

The Horizon Medical Products MicroPort 2 system consist of a low profile ellipsoidal port made of Titanium and an attachable Polyurethane catheter. The catheter is attached to the port body by placing the catheter and strain relief connector over the barbed stem (outlet tube) of the body. The port body is implanted in the mid-arm (above the elbow). Implantation in the mid-arm avoids the bend in the elbow, which could place the catheter under added stress. The catheter reaches the central venous circulation via either the basilic or axillary vein. The veins in the upper arm are larger and offer a less tortuous path to the central venous circulation, making insertion easier. Additionally, this catheter route lessens the danger of pneumothorax, hemopneumothorax, air embolism, as well as catheter shear (Note: Catheter does not pass between the clavicle and the first rib.).

The MicroPort 2 Peripheral Access System is packaged without and with kit introducer components. The kit contains basic components required for percutaneous. The system is sterilized by ethylene oxide gas and is labeled as a sterile as well as a single use only device.

Statement of Sterilization

The MicroPort 2 Peripheral Access System products will be included in the Infuse-A-Port product line. The system is labeled as a sterile and non-pyrogenic device. Pursuant to the 510(k) sterility review guidance for sterilized medical devices (February 12, 1990), the following information is provided.

1. **Sterilization Method Used:** The sterilization method used for the Infuse-A-Port product line is treatment with ethylene oxide gas.
2. **Description of Sterilization Validation Cycle:** The validation study for the Infuse-A-Port product line was designed to conform with the March 1988 AAMI "Guideline for Industrialized Ethylene Oxide Sterilization of Medical Devices: Process design, Validation, Control of Routine Sterilization." Specifically the sections dealing with Overkill sterilization.
3. **Sterility Assurance Level (SAL):** HMP will utilize the AAMI overkill method with a SAL of 10^{-6} .

510(k) NOTIFICATION

4. **Description of Package:** The MicroPort 2 Peripheral Access System products will be packaged in the same way and use the same materials as the Infuse-A-Port product line. The configurations are a tray containing device/component(s) sealed with Tyvek that is sealed in a Tyvek bag or outer tray.
5. **Ethylene Oxide Residuals:** The ethylene oxide residual levels will comply with current ANSI/AAMI/ISO 10993-7:1995 guidelines for residual limits for permanent contact devices.
6. **Pyrogenicity Evaluation:** Each sterilization lot will be tested for the presence of pyrogens using the Limulus Amebocyte Lysate Test. The products will be routinely tested in accordance with USP 85, endotoxin test.

Indications For Use

The MicroPort 2 device is indicated for peripheral placement in the arm when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

Contraindications

The MicroPort 2 device should not be prescribed for patients in which the planned drug therapy requires the use of substances known to be incompatible with the materials of construction.

The MicroPort 2 device should not be implanted in patients suspected to have an allergic reaction to the materials of construction or who have exhibited prior intolerance to device implants.

The MicroPort 2 system should not be implanted in the presence of known or suspected infections, bacterium, septicemia or peritonitis, unless access to the vascular system with the MicroPort 2 device is the method by which the infection or sepsis is to be treated.

Substantial Equivalence

The MicroPort 2 Peripheral Access System (Model #'s P11150 and P11150K) is substantially equivalent to the following devices:

1. Sims Deltec
P.A.S. Port, Peripheral Access System
Model #'s 21-4501 & 21-4502

510(k) NOTIFICATION

2. Bard Access Systems
BardPort Slim Titanium Low Profile Implanted Port
Model # 0605550
3. Medi-Tech
R-Port Premier Implantable Vascular Access System
Model # 45-100

A detailed grid comparing the subject device to the substantially equivalent devices is shown in table 4.

The MicroPort 2 Peripheral Access System is packaged without and with kit introducer components. The kit contains basic components required for percutaneous placement. These components are similar to those currently distributed with other HMP port products. All kit components are either pre-amendment devices, or have received a determination of substantial equivalence via the pre-market notification process (See Table 3.). The intended use of each component is the same as for the predicate device on which it is currently used.

Certification, Summary, and Bibliography for the MicroPort 2 System

Horizon Medical Products hereby certifies that a reasonable search has been conducted of scientific information known or otherwise available to it regarding peripherally implantable intravascular access technology. To the best of our knowledge, set out below as part of the 510(k) submission is a summary of and citation to all adverse safety and effectiveness data regarding peripherally implantable intravascular ports, including the MicroPort 2 System. The summary and bibliography are derived from published scientific literature and from unpublished laboratory, preclinical, and clinical data from other peripherally implantable vascular access systems. It should be noted that the data below does not reflect the rate of incidence of the complications and therefore is not an accurate representation of complication rates of peripheral vascular access ports.

Types and Potential Reported Problems

Reported Patient Events

- ▶ Surgical complications (i.e., Risks normally associated with local or general anesthesia, surgery and post-operative recovery.).
- ▶ Intolerance reaction to implanted device.
- ▶ Vascular thrombosis; asymptomatic partial thrombosis.
- ▶ Erosion/perforation of the port through the skin.
- ▶ Infection: exit site, catheter tunnel, port pocket.
- ▶ Systemic infection or sepsis; bacteremia.
- ▶ Obstruction/occlusion: thrombosis, precipitation, malposition.

510(k) NOTIFICATION

- ▶ Dislodgement due to Twiddler's Syndrome.
- ▶ Skin erosion, cracking, irritation, necrosis; edema/erythema; minor skin breakdown at the site of needle insertion; hematosis.
- ▶ Extravasation causing local inflammatory reaction with or without which may lead to tenderness, pain, and/or parathesia; burning or stinging at the infusion site.
- ▶ Phlebitis.
- ▶ Embolus.
- ▶ Brachial nerve plexus.
- ▶ Difficulty accessing port.
- ▶ Thrombophlebitis.
- ▶ Bleeding.
- ▶ Local cellulitis around the exit site of the catheter.
- ▶ Persistent withdrawal occlusion; may be related to thrombotic occlusion of the catheter tip.
- ▶ Tendon or nerve damage.
- ▶ Cardiac decompensation.
- ▶ Respiratory distress.
- ▶ Pain during infusion; pain in the access extremity.
- ▶ Cardiac arrhythmias
- ▶ Right atrial puncture.
- ▶ Vein puncture.
- ▶ Hemothorax.
- ▶ Cardiac tamponade.

Reported device events

- ▶ Extravasation/infiltration from port due to: needle dislodgement, catheter tip dislodgement/displacement, inadequate needle stabilization, inadequate location of the portal body, or catheter damage.
- ▶ Catheter kinking/knotting.
- ▶ Catheter embolus.
- ▶ Insertion malposition.
- ▶ Thrombosis of catheter.
- ▶ Embolism of catheter.
- ▶ Device occlusion.
- ▶ Catheter disconnection between portal and catheter.
- ▶ Catheter migration; port leakage; septal rupture.
- ▶ Fragmentation of the silicone septum.
- ▶ Poor catheter placement.
- ▶ Fibrin sheath formation on the catheter and/or catheter tip.
- ▶ Device movement, rotation, or extrusion.
- ▶ Catheter malposition, shear, fracture, occlusion, dislodgement, leakage, or rupture.
- ▶ Resistance to infusion-catheter not patent; difficulty drawing blood.
- ▶ Needle puncture to catheter.
- ▶ Catheter shear, fracture, pinch-off

**REFERENCES FOR IMPLANTABLE PERIPHERAL VASCULAR
ACCESS PORTS**

Andrews, J.C., Walker -Andrews, S.C. and Ensminger, W. Long-term venous access with a peripherally placed subcutaneous infusion port: Initial Results. *Radiology* 1990; 176: 45-47

Camp-Sorrell, D. Implantable ports-Everything You Always Wanted to Know. *Journal of Intravenous Nursing* September/October, 1992; 15(5): 262-273

Finney, R., Albrink, M.H., Hart, M. and Rosemurgy, A. A Cost-effective Peripheral Venous Port System Placed at the Bedside. *J Sur Res*, 1992; 53: 17-19

Krawazak, H.W., Strosche, H., Buchholz, J. and Jakel, F. Implantation technique and complications of totally implanted arterial access systems for long-term therapy in patients with occlusive vascular disease. *Journal of Cardiovascular Surgery*, Nov-Dec, 1989; 30(6): 921-4

McKee, J. Future Dimension in Vascular Access Peripheral Implantable Ports. *Journal of Intravenous Nursing*, Nov-Dec, 1991; 14(6): 387-93

McIntosh, B. and Dulchavsky, S. Peripheral Vascular Cutdown. *Procedures in the ICU*, Oct, 1992; 8(4): 807-818

Walker-Andrews S.C., Andrews J.C., Knutsen C. et al. A new Subcutaneous Infusion Port for Simplified Long-term Venous Access. In: Ensminger, W.D., Selam, J.L., eds. *Update in drug delivery systems*. Mt Kisco, NY: Futura, 1989; 45-52

Winters, V., Peters, B., Coila, S. and Jones, L. A trial with a new Peripheral implanted Vascular Access Device. *Oncology Nursing Forum*, 1990; 17(6): 891-896

**FEB 1 0 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Tartal
Quality/Regulatory Affairs Director
Horizon Medical Products, Incorporated
1 Horizon Way
Manchester, Georgia 31816

Re: K994196
Trade Name: Horizon Medical Products Microport 2
Peripheral Access System
Regulatory Class: Unclassified
Product Code: LJJ
Dated: December 10, 1999
Received: December 13, 1999

Dear Mr. Tartal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

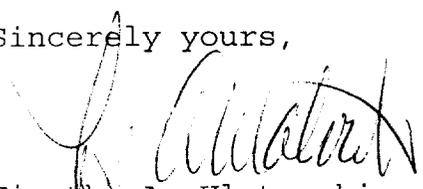
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K994196

DEVICE NAME: Microport 2 Peripheral Access System

INDICATIONS FOR USE:

The *MicroPort 2* System is indicated for peripheral placement in the midarm, above the anticubital space and well below the subaxillary area, when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1)

Patricia Cucumotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994196