Section 10

510(k) Summary

MAY 22 2009

PHS Medical GmbH
Leipziger Str. #246
DE 34260 Kaufungen
Germany

PHS Medical GmbH
Premarket Notification 510(k) Summary
for the
"Power Injectable" C-PortHP Family of Implanted Vascular Access Devices

Part I
General Information

1.	**Submitter name:**	PHS Medical GmbH
2.	**FDA Establishment Number:** **Owner / Operator Number:**	3004407880 9075683
3.	**Address:**	Leipziger Str. #246 DE 34260 Kaufungen Germany
4.	**Phone:**	011-49-5605-94.96.25
5.	**Fax:**	011-49-5605-94.96.99
6.	**Contact person: Company** **: U.S. Agent**	Peter Hankel-Shepherd Donald F. Hults 2360 Johnson Road Southlake, TX 76092 214-549-9208
7.	**Date prepared:**	March 2, 2009

8. **Device trade or proprietary name:**

C-Port^{HP} "Power Injectable" Port (family of Vascular Access Devices)

9. Device common name or usual name:

Implantable Infusion Ports

10. Device classification name:

Port and catheter, implanted, subcutaneous, intravascular (85-LJT)

11. Device classification:

The device is a Class II Device

12. Substantial equivalency:

Claimed against the following device(s):

- C-Port (#K030636, 2003)
- Bard Access Systems PowerPort (#K060812, 2006)
- MEDCOMP ProFUSE^{CT} (#K070003, 2007)

13. Type of medical device:

The PHS Medical GmbH family of "Power Injectible" Vascular Access Devices is a group of subcutaneously implantable ports with an attachable catheter for application by physicians in indicated therapies. The C-Port^{HP} "Power Injectable" Port is intended to be used with an appropriate pressure injectable non-coring needle infusion set.

14. Description of Device:

CAUTION: The device is to be used by or on the order of a physician.

The device has a port that is a titanium chamber with a silicone membrane designed for repeated needle insertion. The port comes in a standard size to enable use with adult patients. A standard profile is preferable so the chamber size is maximized. The port is connected to a catheter that is long enough to insert into the vena cava for positioning to enable fluid infusion into the heart and larger vessels. The catheter is fixed to the port with a catheter lock during a procedure to implant the device. The catheter has a series of radiopaque marks to enable depth determination when the catheter is inserted into the vena cava. A kit is provided to aid in catheter placement, insertion, and port implantation for those ports that are labeled "sterile, single use". For product supplied as OEM bulk, non-sterile, the product is vacuum-packaged in a double bag format and labeled appropriately (relabeler to kit and sterilize). Items such as syringes, vein introducers, trocars, guide wires, sheaths, fixation hubs, Huber needles, and infusion sets may be part of a total kit intended for sterilization.

15. Indications for use statement and product function:

The C-Port^{HP} "Power Injectable" Port family of Vascular Access Devices will be used as a subcutaneously implanted device where repeated access to the vascular system is the therapy of choice for delivery of medications, fluids, nutritional liquids, and special fluids such as contrast enhancement fluids or for withdrawal of blood.

When used with a power injectable needle infusion set, the C-Port^{HP} "Power Injectable" Port is indicated for power injection of contrast media using an 8.0Fr or 9.6Fr catheter. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle or 2ml/s with a 22 gauge non-coring power injectable needle.

The C-Port^{HP} "Power Injectable" Port family of ports and catheters provides a simple method for delivery of volumes of specified fluids via a chamber leading to a catheter and opening into a large vessel in the body. The catheter is inserted into a large vessel and terminated in the superior vena cava. The port is implanted subcutaneously in the soft tissue near the clavicle on the patient's right upper chest wall. Medications or fluids can then be provided as necessary.

16. Contraindications or cautions for use:

A complete listing of the possible complications in the implantation and use of the C-Port^{HP} "Power Injectable" Port family of ports is listed in the USER'S MANUAL which is supplied with any sterile product. Possible complications in the use of the C-Port^{HP} "Power Injectable" Port include, but are not limited to, infection, erosion, extrusion of the device, hematomas, clot formation, thrombosis, catheter fragmentation, and embolization, and occlusion. Improper placement of the catheter in the body has been shown to cause the catheter to be severed from a "pinching" effect by the clavicle and the first rib. **In the placement of the catheter into the vein and on into the superior vena cava, caution should be exercised to be sure that the catheter does not pass between the clavicle and the first rib.**

17. Methods (ways) of application:

The method of application is to prepare and insert the catheter into the vein (by "cut down" method or "percutaneous" method) and on into the vena cava. Then the proximal end of the catheter is tunneled subcutaneously to an area of cut down where the port is to be placed beneath the skin and secured to the fascial layers of tissue. The catheter is joined to the port and the port is secured to the tissue. All wounds are then closed normally.

Intravenous fluids, medications, blood products, or nutritional fluids may then be administered by needle puncture of the septum in the port or periodic blood samples may be acquired if appropriate flushing techniques are followed (instructions for this are found in the USER'S MANUAL).

When used with a power injectable needle infusion set, the C-Port^{HP} "Power Injectable" Port is indicated for power injection of contrast media. For power injection of contrast media, using only an 8.0Fr or 9.6Fr catheter, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle or 2 ml/s with a 22 gauge non-coring power injectable needle.

18. Special precautions for disposal of the device or emptied packages (container):

The sharps used in the procedure should be disposed of according to institution policy. Any remaining parts or empty packages do not require special handling when disposing.

19. Information on sterilization method(s):

a) For sterile products:

All C-Port^{HP} "Power Injectable" Port family products that are intended to be "sterile, single use" are manufactured by PHS Medical GmbH and are sterilized by ethylene oxide gas. Sterilization details for validation, verification, bioburden, etc. can be found in the section on Risk Assessment (7.0) and Sterilization (8.0) in the PHS Medical GmbH 510(k).

b) For non-sterile products:

The C-Port^{HP} "Power Injectable" Port may be supplied in bulk, non-sterile format to a contracted OEM customer so they can relabel, kit and sterilize. Each group of ports intended for OEM sale is double-bagged under vacuum, appropriately labeled, and boxed for shipment. Any recognized open or damaged packaging should be noted, instructions in the warranty labeling followed, and the product returned for evaluation and potential repackaging or disposal.

20. Validity period:

As long as the package/product is unopened and undamaged the product is valid. The materials that make up the components of the C-Port^{HP} "Power Injectable" Port family of products do not deteriorate over time.

21. Special precautions for handling and transportation:

Keep product dry. Product must be stored in an environment that is temperate (+6° C/+43° F – +35° C/95° F). Do not open the package prior to use.

22. Description of package:

A C-Port^{HP} "Power Injectable" Port product (port and catheter) is a basic "cut-down" set with the catheter and port included. The set is packaged in a plastic tray with:

a) 1-Huber point needle (straight needle)
b) 1-Vein pick (retraction/introducing device)
c) 1-Tunneling trocar (atraumatic tip)

d) 1-Blunt needle
e) 1-10 ml Syringe
f) 1-Locking mechanism
g) 1-Patient chart sticker
h) 1-Directions for Use

The plastic tray is heat sealed in a polyethylene/nylon Tyvek header bag (pouch) and sterilized. If requested, a percutaneous introducer kit is included in the C-Port^{HP} "Power Injectable" Port package. This Port/Introducer Set is listed with its own catalog number and must be ordered as such. These sets may be ordered separately or together per physician choice.

The percutaneous introducer kit, or "complete kit" as described in the brochure, contains:

a) 1-Basic set
b) 1-"Split-Sheath" introducer
c) 1-J-Flex Guide Wire with thumb advancer
d) 1- Introducer needle

In addition, the C-Port^{HP} "Power Injectable" Port "complete kit" is packaged with a User's Manual and Patient Implant stickers.

Each kit is packaged in an external fiberboard box. Each box is labeled appropriately to match the item inside the box.

23. Labeling:

Each product is labeled on its plastic container with a stick-on label containing the following information:

Company Name, Location, Contact Number
Product Name by Brand Name and Common Name
Model No.
Size of catheter
Lot Number registration
Units/package indicator
Restricted Device: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
Sterile in unopened undamaged package
For single use only
Package contains information as noted in item 22 above

24. Instructions:

Detailed instructions for use and care of the C-Port^{HP} "Power Injectable" Port are in the USER'S MANUAL. A simple listing of implant instructions is noted here:

Before implanting inspect the port. Do not use if holes, cracks, or surface contaminants are visible.

Flush all air from the port prior to placement using the 20ga. Huber point needle and syringe with heparinized saline.

The selected site for the reservoir body should be over a bony structure and in a location both convenient and comfortable for the patient.

Place the catheter into the vein using the "cut-down" technique or by using a percutaneous introducer.

Place the tip of the catheter in an area of high blood flow when placing it in the venous system. Fluoroscopy is recommended to verfiy proper placement of the catheter tip in the superior vena cava.

Take care not to serrate the catheter tip or occlude it during the catheter placement process. Leave sufficient slack upon placement so patient movement does not stress the catheter.

Position the pocket for the reservoir so that the suture line is not directly over the port. Do not place the port too deep or too shallow. A depth of approximately 5mm under the skin surface is recommended as the optimal placement depth.

Cut the catheter to the proper length and moisten all components with saline.

Slide the catheter lock over the catheter.

Slide the catheter over the bulbed outlet tube (pin connector) of the reservoir.

Slide the catheter lock and catheter forward until the catheter and the outlet tube are completely covered.

Test by gently tugging on the catheter.

Secure the port to the underlying fascia with at least three non-absorbable sutures.

After suturing has been satisfactorily completed, flush the incision with an appropriate antibiotic to ensure a sterile pocket.

Before closure, check patency and flow through the C-Port^{HP} "Power Injectable" Port by x-ray, fluoroscopy, or by an imaging technique of choice.

After each use, always leave C-Port^{HP} "Power Injectable" Port filled with a heparinized saline solution in a concentration recommended by your institution.

If the C-Port^{HP} "Power Injectable" Port is to be used for "power injection" of special fluids, a power injectable needle infusion set must be used. The C-Port^{HP} "Power Injectable" Port is intended to be used with an 8.0Fr or 9.6Fr catheter. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19 or 20 gauge non-coring power injectable needle or 2 ml/s with a 22 gauge non-coring power injectable needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PHS Medical GmbH
C/o Mr. Donald F. Hults
DFH Associates
2360 Johnson Road
Southlake, Texas 76092

MAY 22 2009

Re: K091099
Trade/Device Name: C-Port^{HP} "Power Injectable" Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: March 23, 2009
Received: April 16, 2009

Dear Mr. Hults:

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 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.

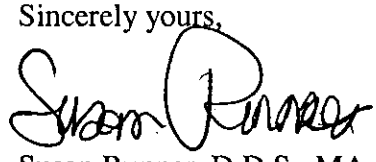
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K091099

Device Name: C-Port^{HP} "Power Injectable" Port (family of Implanted Vascular Access Devices)
Port and catheter, Implanted, Subcutaneous, Intravascular – LJT

Indications for Use:

The C-Port^{HP} "Power Injectable" Port (family of products) will be used as a subcutaneously implanted device where repeated access to the vascular system is the therapy of choice for delivery of medications, fluids, special fluids such as contrast enhancement fluids or for withdrawal of blood.

When used with a power injectable needle infusion set, the C-Port^{HP} "Power Injectable" Port is indicated for power injection of contrast media using an 8.0Fr or 9.6Fr catheter. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle or 2 ml/s with a 22 gauge non-coring power injectable needle.

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

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

Concurence of CDRH, Office of Device Evaluation (ODE)

ivision Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

(Optional Format 3-10-98)

)(k) Number: K091099

510(k) Number (if known): _____

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For CT diagnostic procedures, it is recommended that the number of CT "power injections" be limited to a maximum number of ten (10) accesses over the life of the device.

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

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

Concurence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091099

(Optional Format 3-10-98)