510(k) Summary

General Information

Classification: Class II

NOV - 5 2007

Trade Name: V-Cath Poly PICC

Submitter: HDC, Corporation.
628 Gibraltar Court
Milpitas, CA 95035, USA

Contact: Earl Smart
QA
Tel # (408) 942-7340

Device Identification

A. Common Name: Power-V PICC

B. Classification Name: Percutaneous Implant, long-term intravascular catheter

C. Regulation Number: 880.5970

D. Panel: General Hospital

E. Product Code: LJS

F. Class: Class II

Predicate Devices

V-Cath Poly PICC from HDC Corporation, K033853
OMNIPICC P.I. from RITA Medical Systems, Inc., K051102
OMNIPICC P.I. from RITA Medical Systems, Inc., K062579
PowerPICC Catheter, Bard Access Systems, Inc., K033389

Device Description

The Power-V PICC is a family of peripherally inserted central venous catheters designed to allow for contrast media studies. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each Power-V PICC has a kink resistant, reverse tapered catheter design. The Power-V PICC is indicated for dwell times greater than 30 days. The Power-V PICC catheter assemblies have been tested to withstand power injection of worst-case viscosity injection media at 5 cc/sec with a maximum power injection pressure of 300 psi (see Appendix B). The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations (see Appendix C).

The Power-V PICC is illustrated in the drawings at the end of this section. The Power-V PICC product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen. All catheters are 60 cm long. The catheters are attached to an injection-molded polyurethane hub that has extension legs with luer lock fittings for access attachment.

K071875

Intended Use

The Power-V PICC is indicated for patients that require repeated venous access for infusion or injection therapy. The Power-V PICC is indicated for peripheral access to the central venous system for intravenous therapy. The Power-V PICC is indicated for dwell times less than or greater than 30 days. The maximum recommended infusion rate is 5 ml/sec. The maximum pressure of power injectors used with the Power-V PICC catheter may not exceed 300 psi.

Biocompatibility

Biocompatibility testing on the device was in conformance with ISO 10993-1, and GLP TRIPARTITE. The device is identical to the previously approved device OMNIPICC P.I. from RITA Medical Systems and made by Health Line International Corporation. The device is now made for HDC Corporation by Health Line International Corporation.

Device Performance/Product Testing

The Power-V met all functional requirements and specifications.

Technology Characteristics

The Power-V is equivalent technologically to the devices mentioned under predicate devices above.

Substantial Equivalence

The design, methods of manufacturing, and materials used in the Power-V device are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Mr. Earl Smart
Quality Assurance
HDC Corporation
628 Gibraltar Court
Milpitas, California 95035

Re: K071875
Trade/Device Name: V-Cath (Polyurethane) Power PICC (Power –V)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 3, 2007
Received: October 5, 2007

Dear Mr. Smart:

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,

Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071875
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Indications For Use

510 (K) NUMBER:	K071875
Device Name:	V-Cath (Polyurethane) Power PICC (Power-V)
Indications For Use:	The Power-V PICC is indicated for patients that require repeated venous access for infusion or injection therapy. The Power-V PICC is indicated for peripheral access to the central venous system for intravenous therapy. The Power-V PICC is indicated for dwell times less than or greater than 30 days. The maximum recommended infusion rate is 5 ml/sec. The maximum pressure of power injectors used with the Power-V PICC catheter may not exceed 300 psi.

Prescription Use **X** AND/OROver-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for ADW

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

510(k) Number: K071875