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K051102

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

Submitter's Name / Contact Person

Manufacturer

RITA Medical Systems, Inc.  
One Horizon Way  
Manchester, Georgia 31816

Contact

David Smith  
Director of Vascular Products Engineering  
706-846-3126

General Information

Trade Name	OmniPICC P.I.		
Common Name	Peripherally Inserted Central Catheter (PICC), single and double lumen		
Classification Name	Percutaneous, implanted, long-term intravascular catheter		
	Classification Number:	21 CFR §880.5970	
	Classification Panel:	General Hospital	
	Product Code:	80LJS	
Equivalent Device	Product	Manufacturer	510(k) #
	PowerPICC™ Catheter	Bard Access Systems, Inc	K033389

**Device Description:** The Peripherally Inserted Central Catheter (OmniPICC P.I.) kit includes a catheter and introduction components. The catheter is a percutaneous central venous catheter inserted peripherally. The catheter is comprised of radiopaque polyurethane tubing. The catheter is attached to an injection molded polyurethane hub with extension leg(s) for access via a luer lock device. Each product is packaged in a sterile tray with appropriately sized introducer components. This PICC product line includes externally communicating central venous catheters of 60 cm that is trimmable from the distal end with a single 5 Fr lumen configuration. These are tested to withstand power injection of 5 cc/sec at a maximum power injection setting of 300 psi.

**Intended Use:** The OmniPICC P.I. is intended to be used by medical professionals in patients who require either acute or long-term (chronic) peripheral central venous access for the infusion of medications, nutritional or other parenteral solutions, or blood products, and for the withdrawal of blood samples.

**Indications for Use:** The OmniPICCPI Peripherally Inserted Central Catheter is indicated for use in attaining short and long term vascular access for administration of medications, parenteral nutrition, IV fluids, blood products or blood withdrawal. The catheter may be inserted via the basilic, cephalic and medial veins of the upper extremity. The catheter is intended for implantation dwell time of shorter or greater than 30 days. The maximum recommended infusion rate is 5ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

**Substantial Equivalence Comparison:** The OmniPICC P.I. and its predicate, the Bard PowerPICC™, are identical in intended use and fundamental scientific technology. The two devices are substantially similar in configuration, dimensions, and materials.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David Smith  
Director of Vascular Products Engineering  
RITA Medical Systems, Incorporated  
One Horizon Way  
Manchester, Georgia 31816

Re: K051102  
Trade/Device Name: OmniPICC P.I.  
Regulation Number: 880.5970  
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter  
Regulatory Class: II  
Product Code: LJS  
Dated: October 11, 2005  
Received: October 12, 2005

Dear Mr. Smith:

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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

12051102

# Indications For Use

510(k) Number (if known): K051102

Device Name: OmniPICC P.I.

## Indications For Use:

The OmniPICCPI Peripherally Inserted Central Catheter is indicated for use in attaining short and long term vascular access for administration of medications, parenteral nutrition, IV fluids, blood products or blood withdrawal. The OmniPICCPI is indicated for power injection of contrast media at a maximum recommended infusion rate of 5ml/sec and maximum pressure or pounds per square inch (psi) of 300 psi.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Anthony D. ...*

\_\_\_\_\_  
(Signature Sign-Off)  
Director of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K051102