JUN 6 2002

K021704

Attachment 5

Summary of Safety and Effectiveness

General Provisions	Trade Name: Vaxcel™ PICC Catheter with PASV® Technology.
Name of Predicate Device	PLACEMENT-plus™ [K003642]
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.
Intended Use and Device Description	The Vaxcel™ PICC with PASV® Valve Technology is indicated for use in establishing peripheral access to the central venous system for administration of fluids including, but not limited to, hydration agents, antibiotics, chemotherapy, analgesics, nutritional therapy and blood products. It is also indicated for blood specimen withdrawal. This product is effective for central venous access in adults, children and infants who require intravenous (IV) therapy.
Biocompatibility	Vaxcel™ PICC with PASV® Valve Technology have been tested and compared to the predicate device as per USP (Class VI) and ISO10993. All data demonstrate this device is biocompatible for its intended use.
Chemical Compatibility	All of the materials of the Vaxcel™ PICC with PASV® Valve Technology have been tested against numerous chemicals routinely used in medical applications. All data demonstrate this device is chemically compatible for its intended use.
Summary of Substantial Equivalence	The Vaxcel™ PICC with PASV® Valve Technology has been tested and compared to the predicate device. All data gathered demonstrate this device is substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Mr. Rogers L. Richins
Vice President, Technology & Regulatory Affairs
Catheter Innovations, Incorporated
3598 West 1820 South
Salt Lake City, Utah 84104

Re: K021704
Trade/Device Name: Vaxcel™ PICC with PASV® Value Technology
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: May 21, 2002
Received: May 23, 2002

Dear Mr. Richins:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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): K021704

Device Name: Vaxcel ™ PICC with PASV®Valve Technology

Indications For Use:

Vaxcel ™ PICC with PASV®Valve Technology is indicated for use in establishing peripheral access to the central venous system for administration of fluids including, but not limited to, hydration agents, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. It is also indicated for blood specimen withdrawal.

The product is intended for central venous access in adults, children, and infants who require intravenous (IV) therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021704