

SEP 14 1998

K980566

## SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

### A. GENERAL INFORMATION

Owner Operator Submitting Boston Scientific Corporation  
this Premarket Notification: One Boston Scientific Place  
Natick, MA 01757  
(508) 650.9174

Contact Person: Wanda M. Carpinella  
Regulatory Affairs Department

Device Generic Name: Peripherally Inserted Central Catheter  
Device Classification: 80 FOZ, Intravascular Catheter

### B. INDICATIONS FOR USE

The PICC catheter system is designed for use when central venous catheterization or prolonged intravenous administration of fluids, medications, and/or nutritional therapy is prescribed. A variety of insertion sites may be utilized, depending upon the patient involved and the catheter size selected. While any vessel suitable for insertion may be used, the basilic vein is the most commonly used vein. Location of the distal catheter tip must provide maximum dilution for whatever therapy becomes necessary and assurance of a continued, uncompromised vascular access.

### C. DESCRIPTIVE CHARACTERISTICS

The subject PICC catheter is made from polyurethane material. The catheter shaft has 5 cm incremental markings, which are used to determine the exact catheter trim length. The PICC catheter is offered with or without plastic clamps on the proximal extension tubes.

### D. SUBSTANTIAL EQUIVALENCE

The subject PICC catheter has been shown to be substantially equivalent to the PICC catheter offered by Cook Inc. and Luther Medical.

### E. PACKAGING, STERILIZATION, AND PYROGENICITY

The PICC catheter is packaged in a heat-sealed Tyvek/mylar pouch. The product is sterilized using ethylene oxide gas. Bacterial endotoxin levels are monitored for sterility release purposes.

### F. CONCLUSION

Based on the information presented, Boston Scientific Corporation believes that the PICC catheter meets the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently marketed PICC catheters.

000174



SEP 14 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Wanda M. Carpinella  
Project Manager, Regulatory Affairs  
Boston Scientific Corporation  
One Boston Scientific Place  
Natick, Massachusetts 01760-1537

Re: K980566  
Trade Name: Vaxess Peripherally Inserted Central  
Catheter  
Regulatory Class: II  
Product Code: FOZ  
Dated: July 21, 1998  
Received: July 23, 1998

Dear Ms. Carpinella:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 pre-market notification submission does not affect any obligation you might have under sections 531

Page 2 - Ms. Carpinella

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

*A. Nutman for*

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): New Application *K980566*

Device Name: Peripherally Inserted Central Catheter

**Indications for Use:** The PICC catheter system is designed for use when central venous catheterization or prolonged intravenous administration of fluids, medications, and/or nutritional therapy is prescribed. A variety of insertion sites may be utilized, depending upon the patient involved and the catheter size selected. While any vessel suitable for insertion may be used, the basilic vein is the most commonly used vein. Location of the distal catheter tip must provide maximum dilution for whatever therapy becomes necessary and assurance of a continued, uncompromised vascular access.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*B. [Signature]*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number *K980566*

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  
(Optional Format 1-2-96)