

K 982888

OCT 20 1998

**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: 480 Pleasant Street  
Watertown, MA 02172  
(508) 650.8292  
Contact Person: Christine M. Harris  
Regulatory Affairs Department  
Device Generic Name: Venous Access Port  
Device Classification: 80 LJT, Implanted Subcutaneous Port and Catheter

**B. INDICATIONS FOR USE**

Implantation of a port and catheter is indicated whenever patient therapy requires repeated intravascular injection or continuous infusion of fluids, medications, antibiotics, nutritional and the withdrawal of venous blood samples.

**C. DESCRIPTIVE CHARACTERISTICS**

The port kit provides an implantable port and polyurethane catheter, an introducer sheath/dilator, a 22 Ga. non-coring needle, a 21 Ga. entry needle, a 20 Ga. blunt needle, and 0.018" guidewire.

**D. SUBSTANTIAL EQUIVALENCE**

The proposed venous access port and polyurethane catheter has been shown to be substantially equivalent to the original R-Port Premier and the Gerard Medical TrimPort.

**E. PACKAGING, STERILIZATION, AND PYROGENICITY**

Components comprising the kit are assembled in a PETG blister tray with a snap-fit lid. The tray is placed in a Tyvek/mylar pouch, which is then heat sealed. The kit 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 proposed venous access port meets the minimum requirements that are considered acceptable for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 20 1998

Ms. Laura Mondano  
Manager, Regulatory Affairs  
Boston Scientific Corporation  
One Boston Scientific Place  
Natick, Massachusetts 01760-1537

Re: K982888  
Trade Name: Vaxcel Implantable Vascular Access System  
Regulatory Class: Unclassified  
Product Code: LJT  
Dated: August 14, 1998  
Received: August 17, 1998

Dear Ms. Mondano:

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. However, you are responsible to determine that the medical devices you use as components in the Vaxcel Implantable Vascular Access System have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: if you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your Vaxcel Implantable Vascular Access System. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

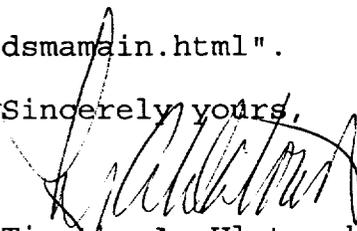
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set

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forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 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 the 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" (21 CFR 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,



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

Device Name: Modified Vascular Access Port and Catheter

Indications for Use: The Vascular Access Port and Catheter is indicated whenever patient therapy requires repeated intravascular injection or continuous infusion of fluids, medications, antibiotics, nutritionals and the withdrawal of venous blood samples.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



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

510(k) Number 4982888