MAY 1 8 2004

Traditional 510(k)
Vaxcel™ Plus Chronic Dialysis Catheter
March 19, 2004

Summary of Safety and Effectiveness

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

General Information

Submitter: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
508-652-5003

Contact Person: Nicholas Condakes

General Provisions

Trade Name: Vaxcel™ Plus Chronic Dialysis Catheter

Classification Name: Catheter and Tunneler , Hemodialysis

Name of Predicate Devices

Vaxcel™ Plus Chronic Dialysis Catheter
Medcomp Split cath II
Bard Hickman catheter

Classification

Class III

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™ Plus Chronic Dialysis Catheter is designed for chronic hemodialysis and apheresis. Catheter lengths of 37 cm and 50 cm are indicated for femoral vein insertion. The major components of the Vaxcel™ Plus Dialysis Catheter are the dual lumen catheter, dead end cap, introducer sheath/dilator, tunneler and CSR wrap.

Summary of Substantial Equivalence

The Vaxcel™ Plus Chronic Dialysis Catheter and tunneler have been tested and compared to the predicate device. All data gathered demonstrate this device as 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

MAY 1 8 2004

Mr. Nicholas Condakes
Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1573

Re: K040736
Trade/Device Name: Vaxcel™ Plus Chronic Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: March 19, 2004
Received: March 22, 2004

Dear Mr. Condakes:

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). 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 kit 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 kit. 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 (PMA), it may be subject to 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known) K040736

Device Name: Vaxcel™ Plus Chronic Dialysis Catheter

Indications for Use The Vaxcel™ Plus Chronic Dialysis Catheter is designed for chronic hemodialysis and apheresis. Catheter lengths of 37 cm and 50 cm are indicated for femoral vein insertion.

(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 Subpart D) (21 CFR 807 Subpart C)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040736