K983039

VII. 510(K) SUMMARY

Manufacturer: SCHNEIDER/NAMIC
Glens Falls, New York 12801

Contact Person: Karin L. Smith
Regulatory Affairs Specialist

Telephone Number: (518) 798-0067
Facsimile Number: (518) 742-4463

Date Prepared: August 28, 1998

Trade Name: Emcee™ Infusion Introducer Sheath Set

Common Name: Catheter Introducer

Classification Name: Introducer, Catheter

Predicate Devices: Emcee™ Introducer Set (K980504)
LocalMed™ InfusaSleeve™ II (K952317)

Intended Use:
The Emcee Infusion Introducer Sheath Set is intended for use in facilitating the percutaneous introduction of catheters, interventional devices and temporary pacing leads into the vasculature. The device also will deliver therapeutic solutions administered through the stopcock sidearm to the vasculature wall surrounding the sheath.

Product Description:
The Emcee Infusion Introducer Sheath Set is comprised of a percutaneous introducer sheath and dilator. The set may also contain a guidewire. The Emcee Infusion Introducer Sheath Set may also be a part of a kit.

Design Features have been added to the Emcee Introducer Set (K980504) to enhance the use of the Introducer Set in facilitating the percutaneous introduction of catheters, interventional devices, and temporary pacing leads into the vasculature. These design features include the addition of sideholes along the sheath shaft in conjunction with a slight reduction in the outside diameter of the dilator (from a point slightly distal to the dilator hub to a point proximal to the sheath tip). These design features permit a fluid path from the sheath sidearm, through the space between the outer dilator wall and the inner sheath wall, and exiting into the vasculature lumen via the sheath sideholes.

VII. 510(K) Summary (Cont.)

The Emcee Infusion Introducer Sheath Set functions equivalently to the Emcee Introducer Set for vasculature access. The dilator/sheath assembly is advanced into the vasculature over a guidewire. The dilator is then removed with the guidewire, leaving the sheath in the vasculature. Devices can now be inserted through the sheath.

When desired by the physician, the sheath-dilator system can be used to deliver therapeutic solutions. Prior to infusing therapeutic solutions, the modified dilator is reintroduced. The therapeutic solution can then be administered via the stopcock on the sheath sidearm, and will be delivered into the vasculature lumen via the sheath sideholes.

Components of the Emcee Infusion Introducer Sheath Set have a lubricious coating for a smooth entrance and removal from the vasculature.

Comparison to Predicate Device:
The Emcee Infusion Introducer Sheath Set indications and design are substantially equivalent to the predicate devices.

Performance Testing:
The Emcee Infusion Introducer Sheath Set has been subjected to non-clinical performance testing to provide data supporting its safety and effectiveness for its intended uses.

Biocompatibility:
The materials used in the Emcee Infusion Introducer Sheath Set have been subjected to biocompatibility testing having its basis in International Standards Organization (ISO) 10993-1 (1992)E "Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests". The Emcee Infusion Introducer Sheath Set is considered to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 7 1999

Ms. Karin L. Smith
Regulatory Affairs Specialist
Boston Scientific Corporation
NAMIC Technology Center
18 Pruyn's Island
Glens Falls, NY 12801-4400

Re: K983039
Trade Name: Emcee™ Infusion Introducer Sheath Set
Regulatory Class: II
Product Code: DYB
Dated: February 4, 1999
Received: February 9, 1999

Dear Ms. Smith:

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 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 (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 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) 594-4586. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Premarket Notification Required Information (Cont.)

INDICATIONS FOR USE

510(k) Number_____

Device Name: Emcee™ Infusion Introducer Sheath Set

Indications For Use:

Intended for use in facilitating the percutaneous introduction of catheters, interventional devices, and temporary pacing leads into the vasculature. The device also will deliver therapeutic solutions administered through the stopcock sidearm to the vasculature wall surrounding the sheath.

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

Concurrence of CDRH, Office of Device Evaluations (ODE)

5/7/99

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983039

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