
IX. 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: May 22, 1998

Trade Name: Emcee Introducer Set

Common Name: Catheter Introducer

Classification Name: Introducer, Catheter

Predicate Devices: MORSE® Hemostatic Catheter Introducer Set (K915078)
Epic™ Introducer Sheath (K960310)
Cook CHECK-FLO® Performer™ Introducer (K895044)
Arrow Radial Artery Catheterization Set (K810675)
Cordis Avanti™ Transradial Sheath Kit (K962746)

Product Description:

The Emcee™ Introducer Set is comprised of a percutaneous introducer sheath and dilator. The set may also contain a guidewire and/or an obturator.

The Emcee™ Introducer Sheath is comprised of an insert molded hemostatic sheath hub and cap design which encapsulates a hemostatic gasket system. The hub also incorporates a sideport extension line with an attached stopcock. The tubing portion of the sheath is percutaneously introduced into the patient's vasculature. The sideport extension is used for purposes of blood access maintenance and fluid administration.

Subsequent to the physician gaining access to the patient's vasculature, a guidewire is inserted into the blood vessel. The Sheath/Dilator combination may be backloaded over the Guidewire to direct the device into the lumen of the vessel. Once the Sheath/Dilator assembly is in place, the dilator and Mini Guidewire (if used) are removed.

PREMARKET NOTIFICATION
K980504 Additional Information

IX. 510(K) Summary (Continued)

The Emcee™ Dilator is a tapered plastic tube with an integral luer hub which is inserted into the Emcee™ Introducer Sheath. The Dilator is longer than the Sheath and with its tapered distal tip, serves to facilitate and support the entry of the Sheath into the patient's vasculature. Once the Emcee™ Introducer Sheath is in place, the Dilator is removed. The Emcee™ Introducer Set will be offered with dilators to accommodate the following guidewire diameters: .018", .025", .032", .035", and .038". Other sizes of dilators will also be provided to address physician preferences.

The Emcee™ Obturator is a plastic tube with an integral luer hub which is inserted into the Emcee™ Introducer Sheath. The Obturator is approximately the same length as the Sheath and is intended to support the tubing portion of the Sheath while the device remains In Vivo.

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

Intended Use:

The Emcee™ Introducer Set is intended for use in facilitating the percutaneous introduction of catheters, interventional devices and temporary pacing leads into the vasculature. Included in this indication are procedures using the radial artery as an access site.

Comparison to Predicate Device:

The Emcee™ Introducer Set design and indications are substantially equivalent to the predicate devices. The manufacturing process, packaging, and sterilization for the Emcee™ Introducer Set mirrors that of SCHNEIDER/NAMIC's currently marketed device.

Performance Testing:

The new Emcee™ Introducer Set has been subjected to non-clinical performance testing to provide data supporting its safety and effectiveness for its intended uses.

Biocompatibility:

Emcee™ Introducer Sets were 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™ Introducer Set is considered to be biocompatible.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 1998

Ms. Karin L. Smith
Regulatory Affairs Specialist
Schneider/Namic
Pruyn's Island
Glens Falls, NY 12801

Re: K980504
Trade Name: Emcee Introducer Set
Regulatory Class: II
Product Code: DYB
Dated: May 22, 1998
Received: May 26, 1998

Dear Ms. Smith:

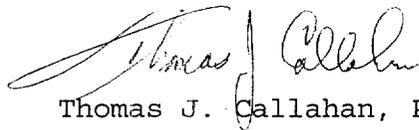
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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/tray. 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) 594-4618. 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" (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, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

II. Premarket Notification Required Information (Continued)

INDICATIONS FOR USE

Page 1 of 1

510(k) Number K980504

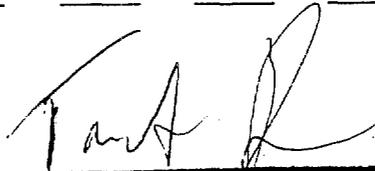
Device Name: Emcee™ Introducer Set

Indications For Use:

Intended for use in facilitating the percutaneous introduction of catheters, interventional devices, and temporary pacing leads into the vasculature (including the radial artery).

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

Concurrence of CDRH, Office of Device Evaluations (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980504

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____