

510(k) Summary, Safety and Effectiveness

Submitter: Baxter Healthcare Corporation
CardioVascular Group
Critical Care
17221 Red Hill Avenue
Irvine, California 92614 USA

Contact: Scott Beggins
Phone: 949-250-2568
Fax: 949-250-3579

Device Trade Name: Baxter Hemostasis Valve Introducers

Common Name: Percutaneous Sheath Introducer

Classification: Class II (Reference 21 CFR 870.1340)

Predicate or Legally Marketed Device: Baxter Healthcare Intro-Flex[®] Percutaneous Sheath Introducer, Cook Critical Care Intro Deuce Hemostasis Valve set and Bard Access Systems Peel-Apart Percutaneous Introducer Kit

Date prepared: May 29, 1998

Device Description:

The Baxter Hemostasis Valve Introducers are used to access the venous system and to facilitate catheter insertion. The introducers are composed of a housing body to which a sheath is attached distally and a side port/extension tube is connected proximally. A valve is located in the housing body to provide a seal around a catheter when inserted through the Introducer and to prevent backflow when no catheter is present. A dilator is provided with the Introducer to ease insertion of the device into the vessel. The Baxter Hemostasis Valve Introducers are provided with and without AMC Thromboshield[™] which is used on Baxter's catheters and introducer products. The device will be packaged in a tray sealed with a tyvek lid and sterilized using 100% ethylene oxide.

Indications for Use:

The Baxter Healthcare Hemostasis Valve Introducers are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

Technology Comparison

The Baxter Hemostasis Valve Introducers are technologically comparable to the predicate devices in construction and physical specifications. Furthermore, design, manufacturing, and sterilization procedures are representative of current industry practices.

Test Summary, In-vitro

Functional testing was performed on the Baxter Hemostasis Valve Introducers to evaluate the integrity and performance of the device. Based upon the results of this testing, the Baxter CardioVascular Group, Edwards Critical-Care has determined that the Baxter Hemostasis Valve Introducers are safe and effective and are acceptable in design and construction for its intended use.

Test Summary, In-vivo

Clinical testing was not performed on the subject catheter because the intended use and indications are the same as the predicate devices. Furthermore, the Baxter Hemostasis Valve Introducers exhibited comparable design characteristics to the predicate devices in the in vitro testing, thus clinical testing was not performed.



NOV 24 1998

Mr. Scott Beggins
Senior Manager, Regulatory Affairs
Baxter Edwards
17221 Red Hill Ave.
Irvine, CA 92614-5686

Re: K981909
Trade Name: Baxter Hemostasis Valve Introducers
Regulatory Class: II
Product Code: DYB
Dated: September 4, 1998
Received: September 8, 1998

Dear Mr. Beggins:

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 (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, 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 premarket notification submission does not affect any obligation

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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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (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,



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

Enclosure

510(k) Number (if known): K981909

Device Name: Baxter Hemostasis Valve Introducers

Indications For Use:

Single Lumen Introducers:

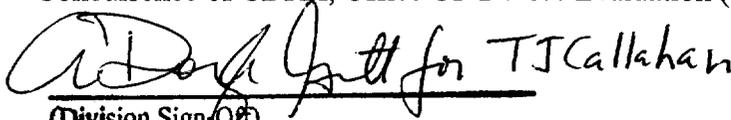
The Baxter Healthcare Single Lumen Hemostasis Valve Introducers are indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

Multiple Lumen Access Products:

The Baxter Healthcare Multiple Lumen Access Products are indicated for use in patients requiring access of the venous system, to facilitate catheter insertion (e.g., pulmonary artery or infusion catheter) and central venous pressure monitoring.

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

Concurrence of CDRH, Office OF Device Evaluation (ODE)



(Division Sign/Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K98 1909
