K033527

FEB - 5 2004

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2597

Contact: Amy Smith, RA Specialist

DEVICE NAME: Intradyn™ Pediatric Hemostasis Introducers

COMMON OR USUAL NAME: Hemostasis Introducers

DEVICE CLASSIFICATION: Catheter Introducer, 21 CFR 870.1340, Product Code DYB

PREDICATE DEVICE:

B. Braun Medical Inc.
Angeion Hemostasis Valve Introducer, K894446

B. Braun Medical Inc.
Braun Hemostasis Introducers, K955820

Daig Corporation
Fast-Cath Hemostasis Introducer, K910861

DESCRIPTION: Hemostasis introducers are used to insert catheters into the vascular system without significant blood loss. The hemostasis valve attached to the sheath is the method of achieving the prevention of blood loss. The valve allows for the introduction of a catheter and provides a tight seal around the catheter being introduced, thus preventing excessive leakage of blood. A procedure to use this device would typically begin with a clinician using an introducer needle to create a puncture hole and then introducing a guidewire into the vasculature. A dilator and sheath are then threaded over the guidewire, and the dilator is removed and discarded. The clinician can then use the introducer sheath with the hemostasis valve to pass catheters through while minimizing blood loss. The introducers are to be used with a catheter of the same size as the designated sheath size, however a catheter one French size smaller may be used with all 4 French and larger introducers.

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The pediatric introducer sets consist of a Teflon introducer sheath, hemostasis valve with a side port extension tube bonded to a three-way stopcock, polyethylene or nylon (3 Fr. Size) dilator and optional guidewire. The pediatric hemostasis introducer sheaths will range in size from 3 – 6 French and will have a sheath length of 7 cm. The guidewire sizes for use with these introducers will be 0.018 – 0.021 inches.

INTENDED USE:

The Intradyn™ Pediatric Hemostasis Introducers is designed to facilitate percutaneous introduction of catheters into the vascular system of pediatric patients while minimizing blood loss.

SUBSTANTIAL EQUIVALENCE:

The Intradyn Pediatric Hemostasis Introducers are identical in materials, functionality, design and manufacturing and sterilization processes to the existing B. Braun Medical Inc. Hemostasis Introducers addressed in submissions K894446 and K955820. The pediatric introducers are similar in indications for use and size to the Fast-Cath introducers currently marketed by Daig Corporation (K910861). The smaller French size that will be available with the new Intradyn Pediatric Hemostasis Introducers is not significantly different than the predicate devices, and does not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

B. Braun Medical Inc.
Ms. Amy Smith
Regulatory Affairs Specialist
901 Marcon Blvd
Allentown, PA 18109

Re: K033527
Trade/Device Name: Intradyn™ Pediatric Hemostasis Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 6, 2003
Received: November 7, 2003

Dear Ms. Smith:

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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 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 and 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 our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K033527

Device Name: Intradyn™ Pediatric Hemostasis Introducer

Indications For Use:

The Intradyn Pediatric Hemostasis Introducers are designed to facilitate percutaneous introduction of catheters into the vascular system of pediatric patients while minimizing blood loss.

(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 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033527