K023253

8.0 510(k) Summary

MAY 0 6 2003

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2280

Contact: Patricia D. Wilson, Regulatory Affairs Specialist

DEVICE NAME: Pediatric Central Venous Catheter Kit

COMMON OR USUAL NAME: Central Venous Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR § 880.5200: Intravascular Catheter

PREDICATE DEVICE:

B. Braun Medical Inc. Soft Tip Multi-Lumen Central Venous Catheter (K971085)

Arrow Pediatric Central Venous Catheterization Kit (The Premarket Notification [510(k) number] for this device is not known]

DESCRIPTION: The Pediatric Central Venous Catheter consists of radiopaque catheter with a flexible soft tapered tip, hub junction, moveable suture wings, extension tubing with removable slide clamps and proximal rigid luer taper hubs. The catheter will be available in sizes ranging from 4 F to 5.5 F, with a double or triple lumen, and useable lengths of 3-1/8" to 8".

INTENDED USE: The Pediatric Central Venous Catheter is a device that is inserted into the venous system for the administration of blood products, parenteral nutrition, I.V. fluids or drugs, for blood sampling, and for central venous pressure monitoring.

SUBSTANTIAL EQUIVALENCE: The Pediatric Central Venous Catheter is similar in design, method of construction, and materials as the Soft Tip Multi-Lumen Central Venous Catheter that was previously cleared under the B. Braun Premarket Notification K971085. The indications for the Pediatric Central Venous Catheter are similar to the indications for the Arrow Pediatric Multi-Lumen Central Venous Catheterization Kit, as noted in product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Ms. Patricia D. Wilson
Regulatory Affairs Specialist
B. Braun Medical Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K023253
Trade/Device Name: Pediatric Central Venous Catheter Kit
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 16, 2003
Received: April 17, 2003

Dear Ms. Wilson:

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) 594-4618. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K023253

Device Name: **Pediatric Central Venous Catheter Kit**

Indications For Use:

The Pediatric Central Venous Catheter is a device that is inserted into the venous system for the administration of blood products, parenteral nutrition, I.V. fluids or drugs, for blood sampling, and for 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)

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

Patricia Cucenite
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023253