K033952

FEB - 4 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: Perifix® Catheter Connector

COMMON OR USUAL NAME: Anesthesia Catheter Connector

DEVICE CLASSIFICATION: Class II per Code of Federal Regulations, Title 21, § 868.5120 – Anesthesia Conduction Catheter, 868.5140 - Anesthesia Conduction Catheter Kit

PREDICATE DEVICE: B. Braun Medical Inc.; Perifix Catheter Connector; **K022019**

DESCRIPTION: The Perifix Catheter Connector is a connecting device used to connect an anesthesia conduction catheter (most commonly an epidural or nerve block catheter) to a luer device for the administration of anesthetic fluids. Catheter connectors are commonly used in epidural anesthesia kits and nerve block kits.

The Perifix Catheter Connector will be available in two different configurations. The first configuration is the one cleared in 510(k) K022019. The second configuration is cleared in the 510(k) K032144. This 510(k) submission is to expand the indications for use for the first configuration to include the 24 Ga. Perifix catheter.

The Perifix Catheter Connector is approximately 1.77 inches long and 0.43 inches in diameter. The connector consists of a luer device on one end for the attachment of a mating luer device, a threading hole, compressible catheter channel and hinged clamp mechanism.

INTENDED USE: A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to 20 - 24 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 20 - 24 gauge Perifix catheters for continuous administration of anesthetic agents.

SUBSTANTIAL EQUIVALENCE:

The Perifix® Catheter Connector indications for use cleared in K022019 are being revised to include use with a 24 Ga. Perifix catheter. The only change to this device is a change to the material of the compressible catheter channel. This change was made due to a reformulation by the supplier. This minor change does not raise any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

B. Braun Medical Incorporated
Amy Smith, RAC
Regulatory Affairs Specialist
MFG. DIV.
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K033952
Trade/Device Name: Perifix Catheter Connector
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSO
Dated: December 19, 2003
Received: December 22, 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.

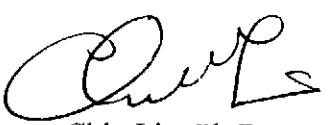
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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,



Chiu Lin, Ph.D.
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): _____

Device Name: Perifix® Catheter Connector

Indications For Use:

A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to 20 - 24 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 20 - 24 gauge Perifix catheters for continuous administration of anesthetic agents.

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K033952