OCT 17 1997

II 510(k) Summary

March 31, 1997

K971233

B. Braun Medical, Inc
824 Twelfth Avenue
Bethlehem, PA 18018
(610)691-5400

CONTACT: Mark S. Alsberge, Regulatory Affairs Director

PRODUCT NAME: Soft Tip Epidural Catheter Kit

TRADE NAME: Anesthetic Conduction Kit

CLASSIFICATION NAME:
Anesthesiology
Class II, 73 CAZ, Anesthetic Conduction Kit
21 CFR 868.5140

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K813186	Perifix Set	B. Braun Medical, Inc.
K801912	Positive Placement Continuous Epidural	Arrow International, Inc.

DEVICE DESCRIPTION:

B. Braun Medical Inc. intends to introduce into interstate commerce the Soft Tip Epidural Catheter Kit. These have the same design, components, and performance characteristics as the catheters currently marketed by B. Braun Medical and covered under K813186 for the Perifix Set. The intended use is for the repeated administration of anesthetic agents into the epidural space. The only difference is the soft tip of the catheter. Soft tip epidural catheters are less traumatic and reduce the incidence of catheter induced paresthesias. Arrow currently markets a Flex Tip Plus epidural catheter which we believe to be covered under K801912.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates

to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to be applicable to patent infringement suits or any other patent matter related to this product or the technology used to manufacture the product.

MATERIAL:

B. Braun Medical certifies that the biocompatibilty tests recommended in the Tripartite Guidance for this category of contact duration will be completed for all the materials used in the manufacture of the device.

SUBSTANTIAL EQUIVALENCE:

The Soft Tip Epidural Catheters Kits are equivalent in materials, form, and intended use to the Perifix Sets currently marketed by B. Braun, Inc., covered under K813186. They are also similar to Arrow's Flex Tip Catheter which we believed to be covered under K801912. The kit components are identical to those items which were offered in the Perifix Kit. There are no new issues of safety or effectiveness raised by the Soft Tip Epidural Catheters.

SAFETY AND EFFECTIVENESS:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; sterility, pyrogenicity (endotoxin/ LAL Method), physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.

III Proposed Labeling

a) Device and Package labels:

A draft sample label for the Soft tip epidural Catheter kit is included in Attachment 1.

b) Manuals and Package Insert:

No additional package insert is planned at this time. A manual is not applicable to this device.

c) Statement of Intended Use:

The soft tip epidural Catheters are intended for the repeated administration of anesthetic agents into the epidural space.

d) Advertisements or Promotional Materials:

No advertisements or promotional materials have been prepared at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Mr. Mark S. Alsberge
B. Braun Medical Incorporated
824 Twelfth Avenue
P.O. Box 4027
Bethlehem, Pennsylvania 18018-0027

Re: K971233
Trade/Device Name: Soft Tip Epidural Catheter Kit
Regulation Number: 868.5140
Regulation Name: Anesthesia conduction kit
Regulatory Class: II
Product Code: CAZ
Dated: July 16, 1997
Received: July 21, 1997

Dear Mr. Alsberge:

This letter corrects our substantially equivalent letter of October 17, 1997.

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 (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 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 continue 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 (240) 276-0120. 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 (240) 276-3150 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

510(k) Number (if known): K971233

Device Name: Soft Tip Epidural Catheter Kit

Indications For Use:

For the administration of anesthetic agents into the epidural space. B. Braun recommends that the epidural catheter be removed or replaced every 72 hours.

(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 [illegible] Anesthesiology, General Hospital,
Infectio[illegible]

510(k) Number: K971233

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

(Optional Format 1-2-96)