II 510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

K964929

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

December 4, 1996

JUN - 2 1997

Contact: Mark S. Alsberge, Regulatory Affairs Manager

Product Name: Peripherally Inserted Central Catheter

Trade Name: Cavafix

Classification name:

Cardiovasular
Class II, 80FOZ
21 CFR 880.5200

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K861479	Cavafix	B. Braun Medical Inc.
UNKNOWN	SoloPICC	SoloPak

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce a Peripherally Inserted Central Catheter.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

Material:

The Peripherally Inserted Central Catheter is composed of materials that have been tested in accordance with and the ISO Standard 10993 for this category. The materials have been determined to be suitable for the intended use of this product.

Substantial equivalence:

The Peripherally Inserted Central Catheter is similar in materials, form, and intended use to the Cavafix cleared by B. Braun Medical Inc. and the SoloPICC manufactured for SoloPak. There are no new issues of safety or effectiveness raised by Peripherally Inserted Central Catheter.

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; 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mark S. Alsberge
Manager, Regulatory Affairs
B. Braun Medical, Inc.
824 12th Avenue
Bethlehem, Pennsylvania 18018

JUN - 2 1997

Re: K964929
Trade Name: ACCUGUIDE® Multilumen Catheter
Regulatory Class: Unclassified
Product Code: LJS
Dated: March 25, 1997
Received: March 28, 1997

Dear Mr. Alsberge:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP

inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 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.

In addition, we have determined that your device kit contains the following which are subject to regulation as drugs:

* alcohol swabsticks,
* Povidone-Iodine swabsticks,
* 10 ml. ampul, 0.9% NaCl,
* skin protectant prep pad,
* Tegaderm™ dressing, and
* 5 ml. ampul of Lidocaine HCl, 1%.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

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 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket

notification" (21 CFR 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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K964929

Device Name: Peripherally Inserted Central Catheter

Indications For Use:

The indication for use is when the patient's condition requires the peripheral infusion of general IV therapy solutions and blood sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cucinotta
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K964929

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)