

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

K971085
June 2, 1997

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

March 7, 1997

Contact: Mark S. Alsberge, Regulatory Affairs Manager
Product Name: Soft Tip Multi-Lumen Central Venous Catheter
Trade Name: Catheter, Percutaneous Intravascular, Long term
Classification name:

Hospital
Unclassified, 80LJS
21 CFR

SUBSTANTIAL EQUIVALENCE¹ TO:

K834473A	Accuguide Multi-Lumen Central Venous Catheter Kit	B. Braun Medical Inc.
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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 Soft Tip Multi-Lumen Central Venous Catheter. A Soft Tip Multi-Lumen 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.

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 Soft Tip Multi-Lumen Central Venous Catheter is composed of materials that have been tested in accordance with the ISO Standard 10993 and have been determined to be suitable for the intended use of this product.

Substantial equivalence:

The Soft Tip Multi-Lumen Central Venous Catheter is similar in materials, form, and intended use to the Accuguide Multi-Lumen Central Venous Catheter Kit cleared by B. Braun Medical Inc. There are no new issues of safety or effectiveness raised by The Soft Tip Multi-Lumen Central Venous 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mark S. Alsberge
Manager, Regulatory Affairs
B. Braun Medical, Incorporated
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

JUN - 2 1997

Re: K971085
Trade Name: Soft Tip Multi-Lumen Central Venous
Catheter
Regulatory Class: Unclassified
Product Code: LJS
Dated: March 11, 1997
Received: March 25, 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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains a 5 ml. ampul of lidocaine and povidone iodine ointment which are subject to regulation as drugs.

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:

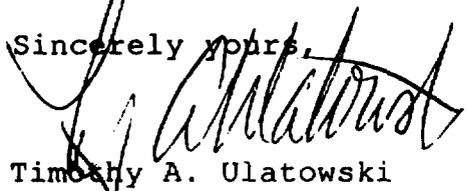
Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

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

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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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 at (301) 443-6597.

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): K971085

Device Name: Soft Tip Multi-Lumen Central Venous Catheter

Indications For Use:

The soft Tip Multi-Lumen Catheter is a device that is inserted into the venous system for the administration of blood products, parenteral nutrition, I.V. fluids or drugs.

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

Center of CDRH, Office of Device Evaluation (ODE)

Patricia Cuanti
Division of ~~Medical~~ Infection Control,
and General Hospital Devices

510(k) Number: K971085

Prescription Use
21 CFR 801.109

OR

Over-The-Counter Use