K041490

OCT 2 9 2004

510(k) Summary

SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 (610) 266-0500, ext. 2376 Contact: Scott Pease, Manager, Regulatory Affairs
DEVICE NAME:	IV Administration Sets with Ultrablock UV-Resistant Tubing
COMMON OR USUAL NAME:	Set, Administration Intravascular
DEVICE CLASSIFICATION:	Class II, 21 CFR §880.5440, Product Code: FPA
PREDICATE DEVICE:	K021480 Codan US Corporation Light-Safe Extension Set (BC565) and Abbott LifeShield® Primary Microbore Device Set
DESCRIPTION:	The IV Administration Sets with Ultrablock UV-Resistant Tubing are a single-use, sterile, non-pyrogenic tubing set intended for the administration of light sensitive solutions from a container to a patient's vascular system. The device is composed of UV-Resistant IV tubing and may include one or more of the following: universal chamber assembly, injection site, male luer lock, slide clamp, 0.2 micron air eliminating filter, flow clip assembly, and pump cassette.
INTENDED USE:	The IV Administration Sets with Ultrablock UV-Resistant Tubing are intended for the pump or gravity administration of IV fluids involving light sensitive solutions.
SUBSTANTIAL EQUIVALENCE:	The B. Braun Medical Inc. IV Administration Sets with Ultrablock UV-Resistant Tubing are similar in indications for use to the Codan US Corporation Light-Safe Extension Set marketed by Codan under their 510(k) Premarket Notification K021480 and the Abbott LifeShield Microbore Device Sets marketed by Abbott Healthcare.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2004

Mr. Scott Pease
Manager, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K041490
Trade/Device Name: IV Administration Set with Ultrablock UV-Resistant Tubing
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 9, 2004
Received: September 10, 2004

Dear Mr. Pease:

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 (240) 276-0115. 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): K041490

Device Name: IV Administration Sets with Ultrablock UV-Resistant Tubing

Indications For Use:

The IV Administration Sets with Ultrablock UV-Resistant Tubing are intended for the pump or gravity administration of IV fluids involving light sensitive solutions.

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

510(k) Number: K041490

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)