JUL 8 2002

K021488

5.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 596-2375

Contact: Sheri L. Musgnung, Manager, Regulatory Affairs

DEVICE NAME:

Surecan™ Safety Huber Needle Infusion Sets

COMMON OR USUAL NAME:

Huber Needle Infusion Sets

DEVICE CLASSIFICATION:

Class II per Code of Federal Regulations, Title 21, § 880.5440, Intravascular Administration Sets, product code FPA

PREDICATE DEVICE:

Millennium Medical Distribution Inc.
Millennium Huber Plus Safety Infusion Set, K993848
Specialized Health Products, Inc.
Liftloc™ Safety Infusion Set, K013394
B. Braun Medical Inc.'s
Introcan® Safety™ IV Catheter, K982805
V2 Injection Site (Ultrasite®) valve, K955585

DESCRIPTION:

The Surecan™ Safety Huber Needle Infusion Set consists of a standard right angle non-coring Huber needle with a passive safety mechanism clip, hub grip, base plate, extension set with an on-off clamp and a female luer lock connector. The Huber needles range in size from 19 Gauge to 22 Gauge and has an overall needle length ranging from ¾ inch to 1-1/2 inch. The Surecan™ Safety Huber Needle Infusion Sets will also be available in two configurations: one with an Ultrasite Valve (previously known as a V2 injection site)/y-site and one without the Ultrasite Valve/y-site.

The safety clip mechanism reduces the risk of accidental needlestick injuries by shielding the needle. The safety clip mechanism will activate once the huber needle is pulled from the base plate.

INTENDED USE:

The Surecan™ Safety Huber Needle Infusion Set is a passive needlestick prevention device which is designed to minimize inadvertent needlesticks. The device is intended to provide implanted subcutaneous port access, used in conjunction with IV administration of chemotherapy and other injectable drugs and/or to withdraw blood.

SUBSTANTIAL EQUIVALENCE:

The Surecan™ Safety Huber Needle Infusion Set is similar in indications for use, has a safety feature to help minimize accidental needlestick injuries, and has a similar design to Millennium Medical Distribution, Inc. Millennium Huber Plus Safety Infusion Set, K993848 and to Specialized Health Products, Inc. Liftloc™ Safety Infusion Set, K013394. The Ultrasite® Valve and the safety clip mechanism that is a component of the Surecan™ Safety Huber Needle Infusion Set are identical to the previously B. Braun Medical Inc.'s premarket notifications, K955585 and K982085. Functional testing was performed to support that there are no new issues of safety or effectiveness raised by the Surecan™ Safety Huber Needle Infusion Set. No sharp injuries or failures of the needlestick prevention feature/safety mechanism occurred.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 8 2002

Ms. Sheri L. Masgnung
Regulatory Affairs Manager
B. Braun Medical, Incorporated
Manufacturing Division
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K021488
Trade/Device Name: Surecan® Safety Huber Needle Infusion Sets
Regulation Number: 880.5965 and 880.5440
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT and FPA
Dated: May 7, 2002
Received: May 8, 2002

Dear Ms. Masgnung:

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 and additionally 21 CFR Part 809.10 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Surecan™ Safety Huber Needle Infusion Sets

Indications For Use:

The Surecan™ Safety Huber Needle Infusion Set is a passive needlestick prevention device which is designed to minimize inadvertent needlesticks. The device is intended to provide implanted subcutaneous port access, used in conjunction with IV administration of chemotherapy and other injectable drugs and/or to withdraw blood.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K021488