K031923

AUG 1 1 2003

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:

Ultrasite® Valve

COMMON OR USUAL NAME:

Needle free Injection Site

DEVICE CLASSIFICATION:

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

PREDICATE DEVICE:

B. Braun Medical Inc.'s Ultrasite Valve (previously known as V2 Injection Site (K955585)

DESCRIPTION:

B. Braun Medical's Ultrasite® Valve is intended for aspiration, injection or gravity/pump flow of fluids upon insertion of a male luer fitting.

The Ultrasite Valve may also be used with power injectors for which the maximum pressure setting is 300 psi. When used with a power injector, the Ultrasite Valve must be secured to other devices with a luer lock connection; other devices must also be rated for 300 psi. The Ultrasite Valve is designed to aid in the prevention of needlestick injury. For more information of the principles of operation, please refer to Attachment I – Proposed Device Labeling and Instructions for Use.

The Ultrasite Valve is designed to provide needle-free access on I.V. pump sets, gravity sets, and extension sets. The Ultrasite Valve is a needle-free,

capless positive displacement valve to be used in place of needles for the administration of fluids. The Ultrasite Valve may be accessed with standard male luer connectors and requires no special accessory devices.

INTENDED USE:

The Ultrasite® Valve is intended for aspiration, injection or gravity/pump flow of fluids upon insertion of a male luer fitting. The Ultrasite Valve may also be used with power injectors for which the maximum pressure setting is 300 psi. When used with a power injector, the Ultrasite Valve must be secured to other devices with a luer lock connection; other devices must also be rated for 300 psi. The Ultrasite Valve is designed to aid in the prevention of needlestick injury.

SUBSTANTIAL EQUIVALENCE:

The subject Ultrasite Valve is similar in materials and design to B. Braun Medical's premarket notification, Ultrasite Valve (previously known as V2 Injection site), K955585. Functional testing was performed to support that there are no new issues of safety or effectiveness raised by the expanded indications for use for power injectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2003

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

Re: K031923
Trade/Device Name: Ultrasite® Valve
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 20, 2003
Received: June 23, 2003

Dear Ms. Musgnung:

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 (301) 594-4618. 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

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031923

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Ultrasite® Valve

Indications For Use:

The Ultrasite® Valve is intended for aspiration, injection or gravity/pump flow of fluids upon insertion of a male luer fitting. The Ultrasite Valve may also be used with power injectors for which the maximum pressure setting is 300 psi. When used with a power injector, the Ultrasite Valve must be secured to other devices with a luer lock connection; other devices must also be rated for 300 psi. The Ultrasite Valve is designed to aid in the prevention of needlestick injury.

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

510(k) Number: K031923

(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)