K073396

510(k) SUMMARY

AUG - 7 2008

APPLICANT/ SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Rebecca A. Stolarick
Director, Regulatory Affairs
Phone: 610-596-2536
Fax: 610-266-4962
E-mail: Rebecca.stolarick@bbraun.com

DEVICE NAME:

B. Braun Medical Inc. Antibacterial Ultrasite® Valve, Ultrasite Ag

COMMON OR USUAL NAME:

Needle Free Reflux Valve or Needleless Access Device

DEVICE CLASSIFICATION:

Class II, Product Code FPA, Intravascular Administration Set, 21 CFR 880.5440

PREDICATE DEVICES:

B. Braun Medical Inc. Ultrasite Valve 510(k) K955585
Elcam Medical Antimicrobial Stopcock 510(k) K053405

DESCRIPTION:

B. Braun's Antibacterial Ultrasite® Valve is an individually packaged, sterile, non-pyrogenic, single use, disposable device. The valve is used as an injection site and requires swabbing to disinfect prior to use. The Antibacterial Ultrasite Valve is a needle free reflux valve or needleless access device intended for IV therapy. The valve is accessed by attaching a male luer fitting.

The Antibacterial Ultrasite Valve contains a silver based compound that is impregnated into the polymeric resin of the device components. The antimicrobial compound is intended to reduce bacterial growth.

INTENDED USE:

The B. Braun Medical Inc. Antibacterial Ultrasite Valve is intended for aspiration, injection or gravity/pump flow of IV fluids upon insertion of a male luer fitting. Not intended for use with power injectors.

The Antibacterial Ultrasite Valve contains a silver based compound which may reduce bacterial growth on the surface and within the fluid path of the device.

Testing with Ultrasite® Ag Valve demonstrated antibacterial effectiveness against *Pseudomonas aeruginosa, Klebsiella pneumoniae,* and *Enterobacter aerogenes* over 96 hours.

The Antibacterial Ultrasite® Valve is not intended to treat existing infections.

SUBSTANTIAL EQUIVALENCE:

The Antibacterial Ultrasite Valve is similar to the predicate device, the currently marketed B. Braun Medical Inc. Ultrasite Valve. The Antibacterial Ultrasite Valve and the Ultrasite Valve are sterile, individually packaged, single use, disposable valves accessed by connecting a male luer fitting. Both are needleless access devices (injection sites) or needle free reflux valves intended for use in IV therapy. The Antibacterial Ultrasite Valve and the Ultrasite Valve have a similar intended use. Both are used for aspiration, injection or gravity/pump flow of IV fluids upon insertion of a male luer fitting.

The Antibacterial Ultrasite Valve and the Ultrasite Valve are composed of the same basic materials and components, have the same design and are manufactured using a similar process. The only difference between the Antibacterial Ultrasite Valve and the Ultrasite Valve is the addition of a silver based antimicrobial compound and a lavender colorant.

The Antibacterial Ultrasite Valve is also similar to the Elcam Medical Antimicrobial Stopcock. Both devices contain the same silver based antimicrobial compound. The intended use of the antibacterial compound in the Antibacterial Ultrasite Valve is the same as the intended use of the antimicrobial compound in the Elcam Antimicrobial Stopcock, to reduce microbial growth.

The Antibacterial Ultrasite Valve was subjected to a variety of tests to demonstrate substantial equivalence with the two predicate devices and to demonstrate the safety and effectiveness of the proposed device. The following tests were conducted: biocompatibility, toxicology, functional performance, package integrity, shipping, microbial ingress challenge, antimicrobial effectiveness, neutralization, and elution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Ms. Rebecca A. Stolarick
Director, Regulatory Affairs
B. Braun Medical Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K073396
Trade/Device Name: Antibacterial Ultrasite® Valve, Ultrasite Ag
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 23, 2008
Received: July 24, 2008

Dear Ms. Stolarick:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073396

Device Name: Antibacterial Ultrasite® Valve (Ultrasite Ag)

Indications For Use:

The B. Braun Antibacterial Ultrasite Valve (Ultrasite Ag) is intended for aspiration, injection or gravity/pump flow of IV fluids upon insertion of a male luer fitting. Not intended for use with power injectors.

The Antibacterial Ultrasite Valve contains a silver based compound which may help to reduce bacterial growth on the surface and within the fluid path of the device.

Testing with Ultrasite Ag Valve demonstrated antibacterial effectiveness against *Pseudomonas aeruginosa, Klebsiella pneumoniae,* and *Enterobacter aerogenes* over 96 hours.

The Antibacterial Ultrasite Valve is not intended for use in the treatment of existing infections.

Prescription Use X 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)

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

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