K083723

JUN - 5 2009

510(k) SUMMARY

APPLICANT/ SUBMITTER:

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

CONTACT:

Bonnie J. Kincaid, RAC
Manager, Regulatory Affairs
Phone: 610-596-2970
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DEVICE NAME: A6 Luer Access Device

COMMON OR USUAL NAME: Needle-free Access Device / Injection Site

DEVICE CLASSIFICATION: Class II per 21 CFR §880.5440, Intravascular Administration Set, Product Code: FPA

PREDICATE DEVICES: B. Braun Medical Inc. Ultrasite® Valve [for use with power injectors (K031923), previously known as B. Braun Medical Inc. V2 Injection Site (K955585)]

DESCRIPTION: B. Braun's A6 Luer Access Device is a positive displacement valve intended to provide needle-free access to IV gravity sets, pump sets and extension sets for the administration of IV fluids and blood. The piston/valve assembly of the A6 is a 3-piece assembly containing an elastomeric piston with a pre-slit septum, which is housed within a clear, rigid body. The A6 requires swabbing to disinfect prior to insertion of a male Luer connector.

The A6 Luer Access Device may be used with power injectors at a maximum pressure of 300 psi and a maximum flow rate of 10 mL/sec. The A6 is individually packaged and is supplied as a sterile, non-pyrogenic, single use, disposable device.

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510(k) SUMMARY (*continued*)

INTENDED USE:

The A6 Luer Access Device is a valve intended for the aspiration, injection or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The A6 Luer Access Device may be used with power injectors at a maximum pressure of 300 psi and a maximum flow rate of 10 mL/sec.

SUBSTANTIAL EQUIVALENCE:

The A6 Luer Access Device has the same intended use and function as the predicate device and is similar to the predicate device in design and materials. Both the proposed and predicate devices are needle-free access devices intended for use in IV therapy. The proposed A6 device and the predicate device are sterile, single use adapters that are used as injection sites when accessed by attaching a male Luer connector to the device. Both the proposed and predicate devices provide needle-free injection sites by means of a positive displacement piston/valve mechanism. Both the proposed and predicate devices may be used with power injectors.

The A6 device was subjected to a variety of tests to demonstrate substantial equivalence with the predicate device, including biocompatibility, package integrity, shipping, microbial ingress challenge and a number of performance tests to verify the safe and effective use of the device. This testing demonstrates that there are no differences between the predicate and the proposed device that raise new issues of safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

Ms. Bonnie J. Kincaid, RAC
Manager, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K083723
Trade/Device Name: A6 Luer Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 28, 2009
Received: June 2, 2009

Dear Ms. Kincaid:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~K083733~~ K083723

Device Name: A6 Luer Access Device

Indications for Use:

The A6 Luer Access Device is a valve intended for the aspiration, injection or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The A6 Luer Access Device may be used with power injectors at a maximum pressure of 300 psi and a maximum flow rate of 10 mL/sec.

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)

for LCDR. Colburn 06/05/09
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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