5. 510(k) SUMMARY

DATE: February 7, 2014

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

Contact: Kimberly Smith, Regulatory Affairs Specialist
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DEVICE NAME: Caresite Luer Access Device

COMMON NAME: Needle-free Injection Site; Needle-free Luer Access Device; Needleless Connector

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

PREDICATE DEVICE:
510(k) Number: K083723
Device Name: A6 Luer Access Device
Classification Product Code: FPA
Regulation Number: §880.5440, Class II
Applicant: B. Braun Medical Inc.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Caresite Luer Access Device (LAD) is a positive displacement needleless connector intended to provide needle-free access to IV gravity sets, pump sets, extension sets and catheters for the administration of IV fluids and blood. The Caresite Luer Access Device (LAD) is a 3-piece assembly containing an elastomeric piston with a slit septum, which is housed within a clear, rigid body. The Caresite Luer Access Device (LAD) requires swabbing to disinfect prior to insertion of a male luer connector. The Caresite Luer Access Device (LAD) does not require a specific clamping sequence or technique in order to be used safely.

The Caresite Luer Access Device (LAD) may be used with power injectors with a maximum pressure rating of 400 psi and a maximum flow rate of 15mL/sec. The Caresite Luer Access Device (LAD) is individually packaged and is supplied as a sterile, non-pyrogenic, single use, disposable device.

INDICATIONS FOR USE

The Caresite Luer Access Device (LAD) is a needleless connector intended for the aspiration, injection or gravity/pump flow of IV fluids and blood upon insertion of a male luer connector. The Caresite Luer Access Device (LAD) may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 15 mL/sec.

SUBSTANTIAL EQUIVALENCE

The B. Braun Medical Inc. Caresite Luer Access Device (LAD) is substantially equivalent to the predicate device having similar indications for use, technological properties and performance.

Technical Characteristics

The Caresite Luer Access Device (LAD) has similar physical and technical characteristics to the predicate device. Both the Caresite Luer Access Device (LAD) and the predicate device are comprised of a body, piston and luer nut. Both devices are comprised of similar materials and components.

Performance Data

Biocompatibility and performance testing was performed on the Caresite Luer Access Device (LAD) to support substantial equivalence to the predicate device. Biocompatibility testing was performed in accordance with ISO 10993-1. Performance testing was performed to demonstrate safety and effectiveness.

CONCLUSION

Based on the results of biocompatibility and performance testing, the proposed B. Braun Medical Caresite Luer Access Device (LAD) is considered substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

B. Braun Medical Incorporated
Ms. Kimberly Smith
Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, PA 18109

Re: K140311
Trade/Device Name: Caresite Luer Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 7, 2014
Received: February 7, 2014

Dear Ms. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Caresite Luer Access Device

Indications for Use *(Describe)*
The Caresite 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 Caresite Luer Access Device may be used with power injectors at a maximum pressure of 400 psi and a maximum flow rate of 15 mL/sec.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman
Date: 2014.05.06
14:53:58 -04'00'