K090905

5. 510(k) SUMMARY

APR 2 7 2009

APPLICANT/ SUBMITTER:

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

CONTACT:

Angela J. Caravella
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DEVICE NAME: addEASE 20mm Binary Connector with 17 Ga. Needle

COMMON OR USUAL NAME: Binary Connector

DEVICE CLASSIFICATION: Class II per 21 CFR § 880.5440
Product Code LHI

CURRENTLY MARKETED DEVICE (PREDICATE): addEASE Binary Connector, 13 and 20 mm (Add-A-Vial II 510(k) K900865)

DESCRIPTION: The addEASE 20 mm Binary Connector with 17 Ga. needle is a double ended transfer device intended to connect a B. Braun 250 mL Excel® IV solution bag to a 20 mm drug vial. The device contains a bag spike on one end and a vial spike on the other end. The vial spike is composed of polycarbonate and the bag spike is composed of a 17 Ga. stainless steel needle. The device contains a plunger which keeps the contents of the connected containers separate until the plunger is purposely deployed and the contents of the bag and vial are mixed. The bag spike and vial spike are protected with caps that maintain the sterility of the device until the caps are removed prior to use.

INTENDED USE: The addEASE 20 mm Binary Connector with 17 Ga. needle is a double ended transfer device intended for use in a pharmacy setting to connect a B. Braun 250mL Excel® IV solution bag to a 20 mm drug vial for reconstituting or mixing the drug in the vial with the solution in the bag.

SUBSTANTIAL EQUIVALENCE:

The addEASE 20mm Binary Connector with 17 Ga. needle has the same intended use and utilizes the same fundamental technology as the predicate device, the currently marketed addEASE device cleared in B. Braun 510(k) K900865 (entitled Add-A-Vial II). The addEASE 20 mm Binary Connector with 17 Ga. needle is similar to the predicate device in material composition and components except for the 17 Ga. needle that replaced one of the polycarbonate spikes. The addition of a 17 Ga. needle to the device does not have a significant impact upon the fundamental technology of the addEASE product. Design verification testing has been completed and all specifications have been met. The testing demonstrated 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

APR 27 2009

Ms. Angela Caravella
Senior Regulatory Affairs Analyst
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K090905
Trade/Device Name: addEASE 20 mm Binary Connector with 17 Ga. Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 27, 2009
Received: April 21, 2009

Dear Ms. Caravella:

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090905

Device Name: addEASE 20 mm Binary Connector with 17 Ga. Needle

Indications For Use:

The addEASE 20 mm Binary Connector with 17 Ga. Needle is a double ended transfer device intended for use in a pharmacy setting to connect a B. Braun 250mL Excel® IV solution bag to a 20 mm drug vial for reconstituting or mixing the drug in the vial with the solution in the bag.

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

510(k) Number: K090905