K100640

5. 510(k) SUMMARY

SUBMITTER:

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

JUL 22 2010

Contact: Matthew J. Homa
Sr. Regulatory Affairs Analyst
Phone: (610) 596-2558
Fax: (610) 266-4962
E-mail: matthew.homa@bbraun.com

DATE: May 17, 2010

DEVICE NAME: 20 mm Vial Fluid Transfer Adapter

COMMON OR USUAL NAME: Set, I.V. Fluid Transfer

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

PREDICATE DEVICE: IV Fluid Transfer Pin, B. Braun Medical Inc, K925401, Class II, LHI and 21 CFR §880.5440.

DESCRIPTION: The 20 mm Vial Fluid Transfer Adapter is a sterile, single use fluid transfer device. The 20 mm Vial Fluid Transfer Adapter is composed of a flexible PVC twist-off cap, PVC tubing, a polycarbonate large bore male luer lock, polycarbonate/LDPE piercing pin, and an inline air filter assembly. The PVC components do not contain DEHP. Components will be solvent bonded to assemble the device. The finished device will be packed and sterilized.

INTENDED USE: The 20 mm Vial Fluid Transfer Adapter is intended for use in transferring IV fluids/medication from a 20 mm drug vial to an IV fluid administration device.

SUBSTANTIAL EQUIVALENCE: The 20 mm Vial Fluid Transfer Adapter has a similar intended use and is comprised of components similar to the IV Fluid Transfer Pin (K925401). Both products have a plastic spike used to access the source container and withdraw IV fluid. Biocompatibility, chemical and functional testing have been completed to verify that there are no differences between the

proposed device and the predicate device which raise new issues of safety or effectiveness.

NONCLINICAL TESTING:

Non clinical testing of the proposed device was conducted to demonstrate safety and effective and substantial equivalence to the predicate device. To verify that the design characteristics and input requirements of the 20 mm Vial Fluid Transfer Adapter are appropriate for the intended use and user requirements, functional performance testing has been executed in the test laboratory. This testing demonstrates that the 20 mm Vial Fluid Transfer Adapter functions as intended. Testing conducted included visual inspection, occlusion, pressure, pull, insertion and retention. The safety of the subject device materials of composition was verified through biocompatibility and chemical testing. All functional performance testing, biological and chemical testing of the materials met the acceptance criteria.

CONCLUSION:

Functional performance testing and material biocompatibility and chemical testing demonstrate that the 20 mm Vial Fluid Transfer Adapter is both safe and effective and performs similarly to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Matthew J. Homa
Senior Regulatory Affairs Analyst
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18196-3941

JUL 22 2010

Re: K100640
Trade/Device Name: 20 mm Vial Fluid Transfer Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: July 16, 2010
Received: July 19, 2010

Dear Mr. Homa:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm 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/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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): _____

Device Name: 20 mm Vial Fluid Transfer Adapter

Indications For Use:

For use in transferring IV fluids/medication from a 20 mm drug vial to an IV fluid administration device.

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
nfection Control, Dental Devices

510(k) Number: K100640