K120150

5. 510(k) SUMMARY

DATE: May 18, 2012

SUBMITTER:

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

MAY 2 4 2012

Contact: Bonnie J. Kincaid
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DEVICE NAME: Dual Spike Transfer Device

COMMON OR USUAL NAME: Fluid Transfer Device

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

PREDICATE DEVICES: B. Braun Medical Inc.'s IV Fluid Transfer Pin, K925401, LHI, 21 CFR §880.5440

DESCRIPTION: The Dual Spike Transfer Device is a device containing two opposing spikes. Each spike contains a second lumen (adjacent to the spike), which facilitates direct flow of fluid/medication from one container (glass or flexible container) to another (glass or flexible container).

The proposed device is designed for use by healthcare professionals during medication preparation, admixture, or fluid transfer. When the Dual Spike Transfer device is attached to the additive container, only air within the vial or flexible container is released into the recipient container. Once fluid transfer is complete, the transfer device attached to the additive container is discarded. This device is intended for admixture only.

The Dual Spike Transfer Device is individually packaged with two guards placed on each spike that provide protection to the spike ends of the device and prevent touch contamination.

INTENDED USE: For the direct transfer of fluids/medications from one rubber-stoppered container to another.

SUBSTANTIAL EQUIVALENCE:

A single predicate, the IV Fluid Transfer Pin, was used for comparison with the proposed device. The Dual Spike Transfer Device has an intended use similar to the IV Fluid Transfer Pin. Both devices are used in admixture programs and they are not intended for direct patient administration. Each of these molded devices has a piercing spike designed for spiking a rubber stopper and a flange to assist in spiking. The spike ends are siliconized and capped by vented molded guards to protect the spike end from damage or touch contamination. The proposed device and the predicate are manufactured in a similar process from similar materials and components. They are both sterile, non-pyrogenic, disposable, single use, individually packaged, fluid transfer devices.

While each device is designed for spiking a rubber stopper, the IV Fluid Transfer Device is also intended to be luer connected to a syringe or other luer compatible container for subsequent transfer to a container. Direct transfer to or from rubber stoppered containers to or from a flexible container can be achieved with the use of the proposed device. Therefore, performance testing has been conducted to support the design and intended use of the device.

CONCLUSION:

Safety and functional testing were conducted on the Dual Spike Transfer Device to demonstrate that the performance of the device and the safety of its materials and components. Results of this testing show that differences between the proposed device and the predicate do not raise new issues of safety or efficacy.

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

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

MAY 24 2012

Re: K120150
Trade/Device Name: Dual Spike Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: May 18, 2012
Received: May 21, 2012

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. 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.

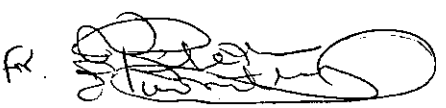
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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: Dual Spike Transfer Device

Indications For Use:

The Dual Spike Transfer Device is intended for the direct transfer of fluid/medication from one rubber-stoppered container to another.

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 Rick Chapman

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

510(k) Number: 120150