K101385

5. 510(k) SUMMARY

June 14, 2010

JUN 2 2 2010

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Senior Manager, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL, 60085
Telephone: (847) 270-4871
Fax: (847) 785-5116

DEVICE NAME:

Trade name:
Dual Luer Lock Cap

Common name: IV Administration Set

Classification name: IV Administration Set, 21 CFR 880.5440, FPA, Class II

PREDICATE DEVICE:

Table 5-1.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
Dual Luer Lock Cap	Baxter Healthcare	K981318	April 22, 1998

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DESCRIPTION OF THE DEVICE:

The subject of this submission is a sterile Dual Luer Lock Cap which will be used to cover male or female Luer ports on medical devices. The proposed Dual Luer Lock Cap will replace the existing Dual Luer Lock Cap and will be sold as a cap to cover an open Luer port after the Luer port has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male Luer lock connection on one end and a female Luer lock connection on the other end.

STATEMENT OF INTENDED USE:

The Dual Luer Lock Cap is indicated for use as a cap for male or female Luer ports on medical devices such as manifolds, stopcocks or sets.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Dual Luer Lock Cap is an injection molded, polypropylene component. The intended use and function of the proposed Dual Luer Lock Cap is identical to the predicate device.

Performance Data: The Dual Luer Lock Cap meets the Bench performance testing requirement according to ISO 594-1:1986 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements* and ISO 594-2:1986 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings* Luer requirements. The Dual Luer Lock Cap is a cap for male or female Luer ports on medical devices.

Biocompatibility: Biocompatibility assessment of the Dual Luer Lock Cap has been conducted based on ISO 10993-1 – Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, external communicating, indirect blood path testing the material used to fabricate the Dual Luer Lock Cap has been shown to be biocompatible and appropriate for its intended use.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests are based on the result of these analyses. All test results meet the acceptance criteria and support that the device is appropriately designed for the intended use. The Dual Luer Lock Cap meets the Bench performance testing requirement according to ISO 594-1 and 594-2 specified as follows:

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- Air leakage
- Separation Force
- Unscrewing torque
- Ease of assembly
- Stress cracking
- Liquid leakage test
- Luer gauging
- Resistance to overriding

CONCLUSION:

The Dual Luer Lock Cap is substantially equivalent to Baxter's current legally marketed Dual Luer Lock Cap cleared April 22, 1998 (K981318).

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

JUN 22 2010

Ms. Nanette Hedden
Senior Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K101385
Trade/Device Name: Dual Luer Lock Cap, Model 2C650
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 14, 2010
Received: June 16, 2010

Dear Ms. Hedden:

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.

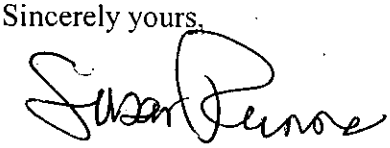
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

INDICATIONS FOR USE

510(k) Number (if known): K101385

Device Name: Dual Luer Lock Cap

Indications for Use:

The Dual Luer Lock Cap is indicated for use as a cap for male or female Luer ports on medical devices such as manifolds, stopcocks or sets.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 6/22/2010

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

510(k) Number: K101385

(Division Sign-Off)
Division of Anesthesiology, General Hospital
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