OCT 18 2011

K112893

5. 510(k) SUMMARY

September 29, 2011

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Senior Manager, Regulatory Affairs
1620 Waukegan Rd. MPGR-AL
McGaw Park, IL 60085
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DEVICE NAME:

Trade name: Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve

Table 5-1.
Clearlink Luer Activated Valve, Representative Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve

Code number	Name
2N8399	Clearlink System Luer Activated Valve for IV Access, Vol. 0.25 mL
2N8378	Clearlink System Non-DEHP Catheter Extension Set, 7.6" (19.3 cm), Vol. 0.9 mL
2N8377	Clearlink System Non-DEHP Y-Type Catheter Extension Set, 6.5" (16.5 cm), Vol. 1.2 mL
2N8374	Clearlink System Non-DEHP Catheter Extension Set, 8.2" (21.0 cm), Vol. 0.5 mL
2N8371	Clearlink System Non-DEHP Y-Type Catheter Extension Set, 6.0" (15.2 cm), Vol. 1.0 mL
2H8401	Clearlink System Non-DEHP Solution Set, 76" (1.9 m)
2C8425s	Clearlink System Solution Set, 100" (2.5 m)

Common name: Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve

Classification name: IV Administration Set (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICE:

Table 5-2.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
Modification to Solution Administration Set with Capped Luer Activated Device (Clearlink).	Baxter Healthcare	K003225	October 19, 2000

DESCRIPTION OF THE DEVICE:

The proposed devices, which are the subject of this Special 510(k) Premarket Notification, consist of the Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve. They are single use disposable devices intended for use with a vascular access device for continuous or intermittent fluid administration or withdrawal of fluids. These devices are the same as the current marketed devices, previously cleared on October 19, 2000 under 510(k) premarket notification "Modification to Solution Administration Set with Capped Luer Activated Device (Clearlink)" by Baxter Healthcare Corporation (K003255).

The Clearlink Luer Activated Valve is an in-line access site and can be connected to male Luer adapters (e.g., syringes or sets) to allow needleless access to the fluid or vascular path.

The IV administration sets with the Clearlink Luer Activated Valve are used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. They contain the Clearlink Luer Activated Valve Y-Site port that can be used for the administration of secondary medication.

The IV extension sets with the Clearlink Luer Activated Valve are used for the administration and withdrawal of fluids. They consist of the Clearlink Luer Activated Valve connected to the IV extension set.

The basis for this premarket notification is a proposed minor design change to Baxter's Clearlink Luer Activated Valve Y-Site design that is integral to the IV administration sets.

STATEMENT OF INTENDED USE:

For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluids.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices consist of the Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve. These devices are the same as the current marketed devices, previously cleared on October 19, 2000 under 510(k) premarket notification "Modification to Solution Administration Set with Capped Luer Activated Device (Clearlink)" by Baxter Healthcare Corporation (K003255). A minor design change will be made to the Clearlink Luer Activated Valve Y-Site design that is integral to the IV administration sets in order to optimize the manufacturing assembly process. The intended use, the basic design, function and the materials for the proposed device are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use. The following bench tests were conducted to evaluate the effect of the design modification on the functional performance of the Clearlink Luer Activated Valve:

- Visual inspection
- Pressure differential test
- Lipid resistance test
- Back pressure test (closed position)
- Back pressure test with male Luer in (open position)
- 6 psi low water pressure seepage test
- Ultrasonic weld joint performance

CONCLUSION:

The proposed devices are substantially equivalent 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

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

OCT 18 2011

Re: K112893
Trade/Device Name: Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 29, 2011
Received: October 3, 2011

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,

Anthony D. Watson

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): K112893

Device Name: **Clearlink Luer Activated Valve, Intravenous (IV) administration and IV extension sets with the Clearlink Luer Activated Valve**

Indications for Use:

For use with a vascular access device for the administration of drugs and solutions. The Clearlink Luer Activated Valve is an in-line injection site, which can be connected to standard male Luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluids.

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)

10/17/11

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

510(k) Number: K112893
