K132734

5. 510(K) SUMMARY

September 24, 2013

OWNER:

Baxter Healthcare Corporation

One Baxter Parkway

Deerfield, Illinois 60015

OCT 08 2013

CONTACT PERSON:

Gary Chumbimune

Manager, Global Regulatory Affairs

32650 N Wilson Road

Round Lake, IL 60073

Telephone: (224) 270-3312

Fax: (224) 270-4900

DEVICE NAME:

Trade name:

Neutral Luer Activated Device (One-Link Needle-free IV connector) and Extension Sets with One-Link Needle-free IV connector

Table 5-1.
Proposed Set Configurations

Code number	Name
2N1333	Non-DEHP Standard Bore Catheter Extension Set, Power Injectable (325 psi, 2241 kPa)
7N8390	One-Link Non-DEHP Microbore Catheter Extension Set, Bonded Needle-free IV Connector with Neutral Fluid Displacement, Power Injectable (325 psi, 2241 kPa)
7N8391	One-Link Non-DEHP Standard Bore Catheter Extension Set, Bonded Needle-free IV Connector with Neutral Fluid Displacement, Power Injectable (325 psi, 2241 kPa)
7N8301	One-Link Non-DEHP Standard Bore Catheter Extension Set, Needle-free IV Connector with Neutral Fluid Displacement, Power Injectable (325 psi, 2241 kPa)
7N8310	One-Link Non-DEHP Microbore Catheter Extension Set, Needle-free IV Connector with Neutral Fluid Displacement, Power Injectable (325 psi, 2241 kPa)

Common name: IV Administration Set

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

PREDICATE DEVICE:

Table 5-2.
Predicate 510(k)

Device	Company	Previous 510(k)	Clearance date
Neutral Luer Activated Device and Extension Sets with Neutral Luer Activated Device	Baxter Healthcare	K120443	May 22, 2012

DESCRIPTION OF THE DEVICE:

The proposed devices, which are the subject of this Special 510(k) Premarket Notification, consist of a power injectable extension set without the One-Link Needle-free IV connector, extension set codes with the One-Link Needle-free IV connector bonded to the rest of the set, standard bore power injectable extension sets, and a power injectable extension set with a one piece male Luer. They are single use disposable devices intended for use with a vascular access

device for the withdrawal of fluids and/or the continuous or intermittent administration of fluids. The proposed devices will provide additional set configurations to clinicians that:

1. Require/prefer the larger bore tubing to infuse fluid via gravity at high rates that cannot be achieved with microbore tubing,
2. Request the use of extension sets with a permanently affixed One-Link Needle-free IV connector.
3. Prefer an extension set without the One-Link Needle-free IV connector.

They may be used with low pressure power injectors having a maximum pressure of 325 psi (2241 kPa) and a maximum flow rate of 10 mL/s. These proposed devices are equivalent to the current marketed devices, previously cleared under 510(k) premarket notification K120443 (cleared on May 22, 2012).

The basis for this premarket notification is the addition of five extension sets to the product line to provide additional options to the clinician. The addition of these five set configurations (3 with standard bore tubing and 2 with microbore tubing) to the product line does not impact the intended use or the fundamental scientific technology of the device. No new materials of construction are being introduced into this device as part of this update.

STATEMENT OF INTENDED USE:

The Baxter Neutral Luer Activated Device is intended for single patient use with a vascular access device for the administration of drugs and solutions without needles, thus eliminating the potential for needle-stick injuries during use. This device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids. This device may be used with low pressure power injectors.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are equivalent to Baxter's currently legally marketed devices cleared on May 22, 2012 (K120443). The addition of five set configurations to the product line does not impact the intended use or the fundamental scientific technology of the device. No new materials of construction are being introduced into this device as part of this update. The intended use, the basic design, function and the materials for the proposed devices 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 their acceptance criteria, and support that the proposed devices are appropriately designed for their intended use.

Performance Data: The following tests were conducted to evaluate the addition of five set configurations to the product line:

- ISO Luer tests on male Luer lock connectors
- Tubing bond strength test on solvent bonds
- Solvent bond pressure test
- Clamp shut-off test
- Power injector compatibility test
- Connector disengagement test
- Post sterilization lipid stress test
- Pressure failure mode simulation
- Burst pressure test

All tests met the acceptance criteria.

Biocompatibility: No new materials of construction are being introduced into these devices as part of this Special 510(k) premarket submission. Biocompatibility assessment has been conducted based on ISO-10993, Biological Evaluation of Medical Devices for prolonged duration, external communicating, indirect blood path and Blue Book Memorandum G95-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," as recommended in the I.V. Administration sets guidance.

CONCLUSION:

The data from the non-clinical tests demonstrate that the proposed devices are as safe and effective, and perform as well as or better to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 8, 2013

Baxter Health Corporation
Mr. Gary Chumbimune
Manager, Global Regulatory Affairs
32650 North Wilson Road
ROUND LAKE IL 60073

Re: K132734
Trade/Device Name: Neutral Luer Activated Device (One-Link Needle-free IV Connector) and Extension Sets with One-Link Needle-free IV Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 30, 2013
Received: September 3, 2013

Dear Mr. Chumbimune:

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K132734

Device Name:

Neutral Luer Activated Device (One-Link Needle-free IV connector) and Extension Sets with the One-Link Needle-free IV connector

Indications for Use:

The Baxter Neutral Luer Activated Device is intended for single patient use with a vascular access device for the administration of drugs and solutions without needles, thus eliminating the potential for needle-stick injuries during use. This device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids. This device may be used with low pressure power injectors.

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
2013.10.03 12:12:15
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K132734