DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 16, 2015

Baxter Health Corporation
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K150860
Trade/Device Name: Nitroglycerin Set with DUO-VENT Spike
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Sets
Regulatory Class: II
Product Code: FPA
Dated: March 30, 2015
Received: April 1, 2015

Dear Mr. Job:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K150860

Device Name
Nitroglycerin Sets with DUO-VENT Spike

Indications for Use *(Describe)*
For the administration of Nitroglycerin solution from a container into the patient's vascular system through a vascular access device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 – 510(k) Summary

April 14, 2015

OWNER:

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DEVICE NAME:

Trade Name: Nitroglycerin Sets with DUO-VENT Spike

Common name: Intravascular (IV) Administration Sets

Classification Panel: 80 General Hospital

Classification: 21 CFR 880.5440

Class: Class II

Product Code: FPA

Table 1. Representative Product Codes for Nitroglycerin Sets with DUO-VENT Spike

Code Number	Name
1C8043	Nitroglycerin Set with DUO-VENT Spike
2C7551	Nitroglycerin Set with DUO-VENT Spike (INTERLINK System)
2C7552	Nitroglycerin Set with DUO-VENT Spike (Needle-Accessed Injection Site)
2C8851	Nitroglycerin Set with DUO-VENT Spike (CLEARLINK System)

PREDICATE DEVICE:

Table 2. Predicate 510(k)

Device	Company	Predicate 510(k)	Clearance date
Nitroglycerine Administration Sets(Solution Admin. Set 2C9096 w/10 PVC).[a]	Travenol Laboratories, S.A.[b]	K832284	December 29, 1983
Solution Sets/Extension Sets	Baxter Healthcare Corporation	K142011	August 18, 2014

[a] Nitroglycerine Administration Sets have been renamed Nitroglycerin Sets with DUO-VENT Spike. K832284 was submitted to the FDA under the device name of Nitroglycerine Administration Sets but was cleared under the device name of Solution Admin. Set 2C9096 w/10 PVC.

[b] Travenol Laboratories, S.A. became Baxter International Inc. in 1988

DEVICE DESCRIPTION:

The proposed devices, which are the subject of this Traditional 510(k) premarket notification, consist of Nitroglycerin Sets with DUO-VENT Spike. They are single use disposable devices intended for the administration of Nitroglycerin solution from a container into the patient's vascular system through a vascular access device. These devices are the same as the current marketed devices, previously cleared under 510(k) premarket notification K832284 (cleared on December 29, 1983).

Baxter's Nitroglycerin Sets with DUO-VENT Spike are comprised of non-DEHP drip chamber with a vented spike, PVC tubing pump segment, polyethylene (PE) lined trilayer tubing, and a luer lock. On all sets there is a fixture slide clamp and an on-off roller clamp. Configurations of these sets differ in overall length, type of injection site (Interlink, Clearlink, needle-accessed, or none), and type of drip chamber (10 or 60 drops per minute).

Polyethylene lined tubing is used to administer Nitroglycerin due to the compatibility issues between the drug and polyvinyl chloride (PVC). Nitroglycerin concentration can be significantly reduced when infused using standard PVC administration sets, due to absorption into the tubing. For this reason, trilayer tubing with an inner polyethylene layer is used in Baxter's line of Nitroglycerin Sets with DUO-VENT Spike.

The basis for this premarket notification is a modification to the PE lined trilayer tubing used in Baxter's Nitroglycerin Sets with DUO-VENT Spike. The modification consists of a change to the Polyethylene material used in the inner layer of the PE lined trilayer tubing.

Along with this modification, the needle-accessed injection site (y-site) is changing from a latex-containing y-site to one that is not manufactured with latex. This proposed needle-accessed y-site is currently used in Baxter's Intravascular (IV) Administration Sets with y-site(s) and has been previously cleared under 510(k) premarket notification K142011 (cleared on August 18, 2014).

These modifications do not impact the intended use or the fundamental scientific technology of the device. No other materials of construction are being introduced into this device as part of this update. The product labels are also being updated to add the indications for use statement of the device, revise statements regarding latex and references to pump devices, and make any other changes to comply with Baxter's labeling standards.

STATEMENT OF INTENDED USE:

For the administration of Nitroglycerin solution from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices are equivalent to Baxter's current legally marketed device cleared under 510(k) premarket notification K832284 (cleared on December 29, 1983). The modification consists of a change to the Polyethylene material used in the inner layer of the PE lined trilayer tubing. In addition to this, the needle-accessed y-sites will be changing, which has been previously cleared under 510(k) premarket notification K142011 (cleared on August 18, 2014). The intended use, the basic design, and function 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 their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

Performance Data:

The following bench tests were conducted to evaluate the effect of the PE lined trilayer tubing modification on the functional performance of the Nitroglycerin Sets with DUO-VENT Spike:

- Clear Passage Test
- Roller Clamp Force Test
- Roller Clamp Shut-Off Test
- Roller Clamp Tubing Leak Test
- Solvent Bond Tensile Strength Test
- Solvent Bond Air Pressure Test
- Drug Compatibility Test

The following bench tests were previously conducted in K142011 (cleared on August 18, 2014) to evaluate the effect of the design modification on the functional performance of the IV Administration Sets with a needle-accessed y-site:

- Puncture Test
- 7-Day Indwell Test
- Burst Test
- Vacuum Leakage Test
- Solvent Bond Tensile Strength Test
- Solvent Bond Air Pressure Test
- Coring Test
- Insertion Force Test

All tests met the acceptance criteria.

Biocompatibility:

Biocompatibility assessments of the Nitroglycerin Sets with DUO-VENT Spike were conducted based on ISO-10993-1, Biological Evaluation of Medical Devices for prolonged duration, external communicating device, indirect blood path, and Blue Book Memorandum G95-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as recommended in the IV Administration Sets guidance, "Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)]". The following tests were conducted:

- Cytotoxicity
- Systemic Toxicity
- Irritation/Intracutaneous
- Sensitization
- Hemocompatibility
- USP Physiochemical

Based upon the results of this prolonged duration, external communicating, indirect blood path testing, the Nitroglycerin Sets with DUO-VENT Spike have been shown to be biocompatible and appropriate for its intended use.

CONCLUSION:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in Table 2.