K103740

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510(k) Summary

JUL 29 2011

for

Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP 5 mL, 10 mL Ampule is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. Not **to be used for any other purposes.**

1. DATE PREPARED

December 20, 2010

2. SPONSOR INFORMATION

A. NAME, ADDRESS AND TELEPHONE/FACSIMILE NUMBER

Spectra Medical Devices, Inc.
260 F & H Fordham Rd.
Wilmington, MA 01887

Contact Person:

Mr. Agustin Turriza

(978) 657-0889 x 225 (telephone)
(978) 657-4339 (facsimile)

aturriza@spectramedical.com

B. OUTSIDE REGULATORY COUNSEL

Foley & Lardner LLP
3000 K St., NW
Suite 500
Washington, DC 20007

Contact Person: David L. Rosen, B.S. Pharm., J.D.

(202) 672-5430 (telephone)
(202) 672-5399 (facsimile)
drosen@foley.com

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3. DEVICE NAME

Proprietary Name:	Sodium Chloride Injection, 0.9%, USP 5 mL, 10 mL Ampule
Common/Usual Name:	Sodium Chloride Injection, 0.9%, USP 5 mL, 10 mL Ampule
Classification Names and numbers:	Saline, Vascular Access Flush Class II, General Hospital, NGT.

4. DEVICE DESCRIPTION AND INTENDED USE

Spectra Medical's Device, Sodium Chloride Injection, 0.9%, USP

5 mL, 10 mL Ampule.

Indications for Use:

The device is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. Not **to be used for any other purposes.**

5. PREDICATE DEVICE

a. K082689 - Sodium Chloride Injection, 0.9%, USP 10 Ml Ampule

K023740 - Syrex Pre-filled Syringe with 0.9% Sodium Chloride

b. Substantial Equivalence Comparison

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Spectra Medical's device, Sodium Chloride Injection, 0.9%, USP 5 mL, 10 mL Ampule is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. Not **to be used for any other purposes.** Spectra Medical's Sodium Chloride Injection, 0.9%, USP is identical to the predicate device. The difference is that the Spectra Medical product is in 5 mL and 10 mL ampules whereas Spectra Medical's previous cleared product was in a 10 mL ampule and the Syrex predicate device is in a syringe.

6. PERFORMANCE CHARACTERISTIC SUMMARY

There has been no change to the performance characteristics of the device system.

7. TECHNOLOGICAL CHARACTERISTICS

There has been no change to the fundamental scientific technology.

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

Spectra Medical Devices, Incorporated
C/O Mr. David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner, LLP
3000 K Street, NW
Washington, District of Columbia 20007

JUL 29 2011

Re: K103740
Trade/Device Name: Sterile Sodium Chloride 0.9% Flush, 5 mL and 10 mL Ampules
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: June 9, 2011
Received: June 9, 2011

Dear Mr. Rosen:

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.

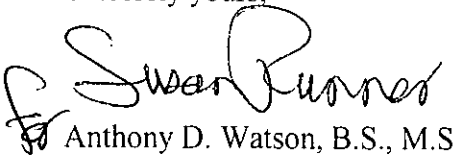
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

510(k) Number (if known) K103740

Device Name: Sterile Sodium Chloride 0.9% Flush, 5 mL and 10 mL Ampules

Indications for Use:

The device is indicated only for use in flushing compatible intravenous tubing systems and in dwelling intravascular access devices. Not **to be used for any other purposes.**

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

Elaine S. Marshall for EFC
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103740