

K113555

510(k) Summary

JAN 30 2012

510(k) Summary of Safety and Effectiveness

As required by 809.92(a)(2).

SPECIAL 510 (k) PREMARKET NOTIFICATION NUMBER: _____

Submitter and Owner of the 510(k)

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Official Correspondent

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Date of Preparation

November 1, 2011

510(k) Application Number

TBD

Trade/Proprietary Name

0.9% Sodium Chloride Flush Syringe

Common Name/Usual Name

Saline Flush Syringe

Device Classification Name

Device, Flush, Vascular Access

Regulation Number

880.5200

Device Class

Class II Device

510(k) Summary

Classification Panel

General Hospital

Classification Product Code

NGT

INDICATIONS FOR USE

Intended use: 0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacture for the appropriate device.

DEVICE DESCRIPTION:

The Predicate Device, 510(k) Number: K111034, AMUSA consists of a plastic syringe filled with 0.9% Sodium Chloride Flush Solution that is terminally sterilized. The predicate device fluid path sterile has a Sterility Assurance Level (SAL) of 10^{-6} . This is a single use device.

The Modified Device, the subject of this 510 (k), consists of a plastic syringe filled with 0.9% Sodium Chloride Flush Solution that is terminally sterilized. The modified device fluid path sterile has a Sterility Assurance Level (SAL) of 10^{-6} . This is a single use device.

TECHNICAL DATA: The technical characteristics for the modified device do not differ from those of the currently marketed device. These devices have the same design, the same fundamental scientific characteristics, the same labeling, and have the same intended use. The proposed modification involves a change in the syringe component supplier.

Substantial Equivalence: Non-clinical verification testing for the proposed change involved chemical-physical, functional, and product stability testing. The results of testing conducted verifies the modified terminally sterilized syringe performed in an equivalent manner to the predicate terminally sterilized syringe and is safe and effective when used as intended.



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

AM USA
C/O Karen Thomison
Director of Quality Assurance
5209 Linbar Drive, Suite 640
Nashville, Tennessee 37211

JAN 30 2012

Re: K113555
Trade/Device Name: AM USA 0.9% Sodium Chloride Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Saline, Vascular Access Flush
Regulatory Class: II
Product Code: NGT
Dated: January 18, 2012
Received: January 19, 2012

Dear Ms. Thomison:

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.

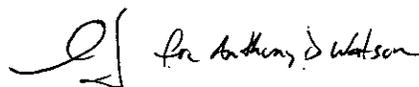
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Indications for Use

Indications for Use Statement

510(k) Number (if known): _____

Device Name: 0.9% Sodium Chloride Flush Syringe

Indications for Use:

"0.9% Sodium Chloride Flush Syringes are intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacture for the appropriate device".

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

R. C. Chapman 1/25/12

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 113555