

AMUSA Sterile/Sterile 510(k)

510(k) Summary

**510(k) Summary of Safety and Effectiveness**

As required by 809.92(a)(2).

SPECIAL 510 (k) PREMARKET NOTIFICATION NUMBER: K120831e

JUL 12 2012

***Submitter and Owner of the 510(k)***

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Nashville, TN 37211  
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***Official Correspondent***

Karen Thomison  
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AMUSA  
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Nashville, TN 37211  
Phone: 615-833-2633  
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***Date of Preparation***

3/13/12

***510(k) Application Number***

***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

## AMUSA Sterile/Sterile 510(k)

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 manufacturer for the appropriate device.

### **DEVICE DESCRIPTION:**

*The Predicate Device*, 510(k) Number: K111034, cleared on July 14, 2011 consists of a plastic syringe filled with 0.9% Sodium Chloride Flush Solution that is terminally sterilized. The predicate device is fluid path sterile with a Sterility Assurance Level (SAL) of  $10^{-6}$ . This is a single use device packaged in a dust cover.

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 has a sterile package that maintains the sterility of the fluid, fluid path and the exterior of the device. The modified device can be used in a sterile field if the package is not open and aseptic techniques are followed. The Sterility Assurance Level (SAL) is  $10^{-6}$ . This is a single use device.

**Technical Data:** The technical characteristics of the syringe for the modified device do not differ from those of the currently marketed device. These syringes have the same design, the same fundamental scientific characteristics, and have the same intended use. The proposed modification involves a change in packaging by substitution the dust cover with a sterile barrier system. The labeling was also changed to include instructions for use in a sterile field. All other aspects of the syringe design remain the same.

**Substantial Equivalence:** Non-clinical verification testing for the proposed change involved chemical-physical, functional, and package validation studies. The result of testing conducted verifies that the change in sterile packaging of the modified device performed in an equivalent manner to the predicate device and is safe and effective when used as intended. Other companies have FDA clearance for special 510(k)s submitted with similar changes.



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. Karen Thomison  
Director of Quality and Regulatory Affairs  
AMUSA  
5209 Linbar Drive, Suite 640  
Nashville, Tennessee 37211

JUL 12 2012

Re: K120836  
Trade/Device Name: 0.9% Sodium Chloride Flush Syringe  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: II  
Product Code: NGT  
Dated: June 11, 2012  
Received: June 13, 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,

For 

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

# 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 manufacturer for the appropriate device".

Prescription Use  X  
(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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off) 7/12/12  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K120836