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

August 31, 2015

Nurse Assist, Inc.
Mr. Brian Cox
Vice President of Operations
4409 Haltom Road
Haltom City, TX 76117

Re: K150143
Trade/Device Name: Normal Saline Flush
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: July 29, 2015
Received: July 30, 2015

Dear Mr. Cox,

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" (21 CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology,
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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)*
K150143

Device Name
Normal Saline Flush

Indications for Use *(Describe)*
This device is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. **Submitter's name and address:**
   Nurse Assist, Inc.
   4409 Haltom Road
   Haltom City, TX 76117

2. **Submitter's telephone number and fax number:**
   Tel: (817) 231-1300
   Fax: (817) 231-1500

3. **Contact person:**
   Mr. Brian Cox – Vice President Operations

4. **Date this 510(k) summary prepared:**
   05/14/15

5. **Regulatory Description:**

Trade name:	Normal Saline Flush
Common Name:	Saline IV Flush
Classification Name:	Saline, Vascular Access Flush
Regulation Description:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Class:	II
Product Code:	NGT

6. **Legally marketed device to which substantial equivalence is claimed:**
   Primary predicate – AMUSA 0.9% Sodium Chloride Flush Syringe, K111034
   Reference device – Kendall Monoject Prefill Flush Syringe, K032438

7. **Description of the device:**
   The subject device is a polypropylene plastic syringe filled with 0.9% Sodium Chloride for Injection, USP, and capped with a polypropylene plastic cap. The device will be terminally sterilized by gamma radiation sterilization. The device will be marketed as a 12 mL syringe with a 3 mL, 5 mL, or 10 mL fill volume.

8. **Intended use and indication for use:**
   For prescription use: This device is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

9. Summary of technological characteristics compared to the predicate device:

	Proposed device	**Primary Predicate K111034**	**Reference Device K032438**
	Nurse Assist Normal Saline Flush	**AMUSA 0.9% Sodium Chloride Flush Syringe**	**Kendall Monoject Prefill Flush Syringe**
Classification Product Code	NGT	NGT	NGT
Intended use:	This device is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.	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.	The syringes are intended for flushing compatible intravenous tubing systems and indwelling intravascular access devices.
Use on sterile field?	No	No	Unknown
Prescription only?	Yes	Yes	Yes
Sterile?	Yes	Yes	Yes
Single use only?	Yes	Yes	Yes
Method of Sterilization	Radiation	Radiation	Steam Autoclave
Shelf life	2 years	2 years	2 years
Chemical composition	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Mechanism of dispensing	12 mL plastic syringe, luer lock tip	12 mL plastic syringe, luer lock tip	12 mL plastic syringe, luer lock tip
Fill Volumes	3 mL, 5 mL, 10 mL	3 mL, 5 mL, 10 mL	3 mL, 5 mL, 10 mL
Barrel, Plunger, Tip Cap, Bag Material	Polypropylene	Polypropylene	Polypropylene
Uses cleared syringe	Yes – K945715	unknown	Yes – K945715
Plunger Grommet Material	This product is not made with natural rubber latex	This product is not made with natural rubber latex	This product is not made with natural rubber latex

10. Non-Clinical Performance Data

Gamma radiation sterilization has been validated for this device. This method provides an SAL of 10^{-6}. The following testing was performed post-sterilization:

NAME	TEST METHOD(S)	RESULTS OVERVIEW
Package Integrity	• Subject device to ISTA 2A 2005 conditioning and testing criteria • Perform post-conditioning testing: o **Visual Inspection of packaging:** confirm package integrity o **Seal (vacuum) testing:** 15 in-Hg for 15 minutes and verify no leaks o **Sterility:** Tryptic Soy Broth & Fluid Thioglycollate Medium	• **Visual Inspection of packaging:** no major compromise of packaging • **Seal testing:** no leaks • **Sterility:** confirmation of sterile barrier and product sterility—no growth present
Shelf Life (Stability)	Post Sterility Testing at T=0, T=1 and T=2 (Note: Accelerated aging for T=1 and T=2): • **Visual:** confirm no leaks, holes or cracks • **Seal (vacuum) testing:** 15 in-Hg for 15 minutes and verify no leaks • **Appearance/Color:** verify clear liquid • **Odor:** confirm objectionable or unusual odors are not present • **pH:** 4.5 – 7.0 • **Sodium Chloride:** 0.885 – 0.945% • **Heavy Metals:** USP <231> and <241> • **Sterility:** Tryptic Soy Broth • **Particulate:** USP <778>	• **Visual:** no leaks, cracks or holes • **Seal:** no leaks • **Appearance/Color:** no discoloration or cloudiness • **Odor:** no objectionable odors • **pH:** within upper and lower limits • **Sodium Chloride:** within upper and lower limits • **Heavy metals:** o USP <231>: less than 10 ppm (0.001%) o USP <241>: less than 2 ppm • **Sterility:** confirmation of sterile barrier and product sterility—no growth present • **Particulate:** less than 3,000 for 10 µm and 300 for 25 µm
Biocompatibility	The classification of the device is: Blood Path, Indirect (limited to ≤ 24 hours). The following tests were performed: • **Cytotoxicity:** ISO 10993-5:2009 • **Hemocompatibility**: ASTM 7756:2008 and ISO 10993-4:2006 • **Acute Systemic Toxicity:** ISO 10993-11:2006 • **Intracutaneous Irritation:** ISO 10993-10:2010 (modified for a chemical solution) • **Contact Sensitization:** ISO 10993-10:2010 • **Pyrogenicity:** USP <151> and ISO 10993-11:2006	• **Cytotoxicity:** Grade 0 (no reactivity) • **Hemocompatibility**: Hemolytic index of 0.0% (non-hemolytic) • **Acute Systemic Toxicity:** Non-toxic • **Intracutaneous Irritation:** Nom-irritant • **Contact Sensitization:** Non-sensitizer • **Pyrogenicity:** Nonpyrogenic
Endotoxin	**USP <85>:** Limulus Amebocyte Lysate (LAL) endotoxin testing using Gel Clot Method (Monograph #85). (Note: test results must be less than 0.25 EU/ml.)	• All samples tested at an endpoint of 0.03 EU/ml • **Sensitivity of Lysate (AntiLog$_{10}$ of Mean):** 0.03 EU/ml.

The test results demonstrate that the device is non-hemolytic, non-toxic, a non-irritant, non-sensitizer, and non-pyrogenic. In addition to the test results noted and highlighted above, the results also demonstrate that packaging integrity and sterility were maintained, and as such, the device met specifications throughout the noted shelf life.

11. Conclusion

The above summarized characteristics and comparisons demonstrate that the Nurse Assist Normal Saline Flush device is as safe and effective as the predicate and reference devices. In summary, the Nurse Assist Normal Saline Flush described in this submission is substantially equivalent to the predicate and reference devices.