DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 31, 2016

North American Rescue, LLC
William Slevin
Director, QA/RA
35 Tedwall Court
Greer, South Carolina 29650

Re: K152340
Trade/Device Name: North American Rescue Sharps Shuttle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: April 28, 2016
Received: April 29, 2016

Dear William Slevin:

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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Dental Devices
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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)*

K152340

Device Name
North American Rescue Sharps Shuttle

Indications for Use *(Describe)*

The North American Rescue Sharps Shuttle is a molded polypropylene, non-sterile, single use, portable transportable sharps container. Its permanent closure system protects the user prior to disposal via incineration.

The North American Rescue Sharps Shuttle is approximately 6.41″ in length, with a sharps aperture of approximately 1″ in diameter.

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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510(k) 152340 Summary

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Sharps Shuttle is provided below.

Date Summary Prepared	May 31, 2016
Manufacturer/Distributor/ Sponsor	North American Rescue 35 Tedwall Court Greer, SC 29650-4791 USA
510(k) Contact	North American Rescue, LLC William Slevin 35 Tedwall Court Greer, SC 29650-4791 864-675-9800 (phone) wslevin@narescue.com (email)
Trade Name	*North American Rescue Sharps Shuttle*
Common Name	Container Sharps
Code –Name –Classification	MMK – Hypodermic single lumen needle - 21 CFR 880.5570: Class II
Predicate Devices	Sage Sharps Shuttle K972279 (ownership acquired by Tyco/now Covidien)
Device Description	Device Description: The North American Rescue Sharps Shuttle are injected or blow molded single use, non-sterile disposable, transportable sharps collectors and transport containers intended for use where standard sharps containers are not conveniently accessible. The North American Rescue Sharps Shuttle is a portable collector that provides an alternate to resheathing a needle with its original protective cover. The North American Rescue Sharps Shuttle is designed to safely hold small low volume sharps such as blood needles, lancets, and small syringes. The North American Rescue Sharps Shuttle is cylindrical, with a conical taper and a temporary closure capability, which can be reopened for the storage of additional sharps prior to terminal disposal via incineration. In addition to the temporary closing mechanism, the North American Rescue Sharps Shuttle has a locking mechanism designed with a locking tab to permanently close the container. The North American Rescue Sharps Shuttle is a non colored, translucent plastic and is approximately 6.41 inches long by 1 inch in diameter. The cap is red opaque plastic with a hinged cap, which is snapped and locked close contains the biohazardous sharps. Each North American Rescue Sharps Shuttle is individually labeled with a biohazard symbol and fill line. The North American Rescue Sharps Shuttle is available as a single device or as a kit of six (6).
Intended Use	The North American Rescue Sharps Shuttle is a molded polypropylene, non-sterile, single use, portable transportable sharps container. Its permanent closure system protects the user prior to disposal via incineration. The North American Rescue Sharps Shuttle is approximately 6.41” in length, with a sharps aperture of approximately 1” in diameter.

Technological Characteristics	The North American Rescue Sharps Shuttle is cylindrical, with a conical taper, a temporary closure capability, which can be reopened for the storage of additional sharps prior to permanent locking.
Non-Clinical Performance Testing Conclusion	The North American Rescue Sharps Shuttle was tested for impact resistance and puncture resistance ASTM F2132-01 (2008)e1 "Puncture of Materials used in Resistance of Materials containers for discarded used in containers for medical needles and other Sharps". ISO 23907 (First edition 2012-09-01) Sharps injury protection — Requirements and test methods — Sharps containers for puncture resistance section 5.3. ISO 23907 (First edition 2012-09-01) Sharps injury protection — Requirements and test methods — Sharps containers for resistance to damage and leakage after dropping, section 5.4.
Substantial Equivalence Summary (Conclusion)	Based on the technological; characteristics and non-clinical performance testing the North American Rescue Sharps Shuttle was shown to be substantially equivalent to the predicate device, the Sage Sharps Shuttle K972279.

Additionally, a comparison between the North American Rescue Sharps Shuttle and the predicate device is summarized below:

Feature	**North American Rescue Sharps Shuttle**	**Sage Sharps Shuttle K972279**	**Substantially Equivalent**
Device Classification	21 CFR §880.5570: Class II	21 CFR §880.5570: Class II	Yes
Product Code	MMK – Container Sharps	FMI – Needle, Hypodermic, Single Lumen	Yes
Device Common Name as Cleared by FDA	Container, Sharps	Container, Sharps	Yes
Indications for use	The North American Rescue Sharps Shuttle is a non-sterile, single use, portable transportable sharps container. Its permanent closure system protects the user prior to disposal via incineration.	The Sharps Shuttle and Sharps Shuttle with locking mechanism are single use, non-sterile, disposable , sharps transport containers for use in any setting where standard sharps containers are not conveniently accessible, such as EMS, home health care, etc.	Yes
Patient Population	Single use only	Single use only	Yes
Environment of Use	Point of procedure - non clinical conditions including first responders at point of care and battlefield medics. Not intended for a stationary horizontal surface.	Point of procedure - non clinical conditions, EMS and home health care. Not intended for a stationary horizontal surface.	Yes

Feature	North American Rescue Sharps Shuttle	Sage Sharps Shuttle K972279	Substantially Equivalent
Device Description	The North American Rescue Sharps Shuttle is portable, transportable sharps container, with a permanent closure system which protects the end user prior to incineration. The North American Rescue Sharps Shuttle are injection molded single use, non-sterile disposable, sharps transport containers intended for use where standard sharps containers are not conveniently accessible. The North American Rescue Sharps Shuttle is a portable, pocket collector that provides an alternate to resheathing a needle with its original protective cover. The North American Rescue Sharps Shuttle is designed to safely hold small low volume sharps such as blood needles, lancets, and small syringes.	The Sage Sharps Shuttle is designed to be used by EMS, home health care etc. The Sage Sharps Shuttle are injection molded single use, non-sterile disposable, sharps transport containers intended for use where standard sharps containers are not conveniently accessible. The Sage Sharps Shuttle is a portable, pocket sharps collector that provides an alternate to resheathing a needle with its original protective cover, which may or may not be accessible and is not a recommended practice. The Sage Sharps Shuttle is designed to safely hold small low volume sharps such as angio-caths, blood needles, lancets, and small syringes.	Yes
Principles of Operation	The North American Rescue Sharps Shuttle is portable, transportable sharps container, with a permanent closure system which protects the end user prior to incineration. The North American Rescue Sharps Shuttle is cylindrical, with a conical taper and a temporary closure capability, which can be reopened for the storage of additional sharps prior to terminal disposal. In addition to the temporary closing mechanism, the North American Rescue Sharps Shuttle has a locking mechanism designed with a locking tab to permanently close the container. The North American Rescue Sharps Shuttle is designed for vertical and horizontal use for storage of blood needles, lancets and small syringes.	The Sage Sharps Shuttle is intended for use by EMS, home health care, etc. where standard sharps containers are not conveniently accessible. The Sage Sharps Shuttle is cylindrical, with a conical taper and a temporary closure capability, which can be reopened for the storage of additional sharps prior to terminal disposal. In addition to the temporary closing mechanism, the Sage Sharps Shuttle has a locking mechanism designed with a locking tab to permanently close the container. The Sage Sharps Shuttle is designed for vertical and horizontal use for storage of angio-caths blood needles, lancets, and small syringes.	Yes
Application	Storage of blood needles, lancets, and small syringes pending terminal disposal.	Storage of angio-caths, blood needles, lancets, and small syringes pending terminal disposal.	Yes

Feature	North American Rescue Sharps Shuttle	Sage Sharps Shuttle K972279	Substantially Equivalent
Volume	Approximately 6.41" (H) (163mm) by 1.33" (W I.D.) (34mm), <0.75l capacity	Approximately 6.385"(H) by 1.11" (W I.D.) , with <0.75l capacity	Yes
Weight	Approximately 1.5oz	Approximately 1.5oz	Yes
Non-Clinical Testing Summary	The North American Rescue Sharps Shuttle was tested for impact resistance and puncture resistance per ASTM 2132-01 (2008)e1 "Puncture of Materials used in Resistance of Materials containers for discarded used in containers for medical needles and other Sharps". ISO 23907 (First edition 2012-09-01) Sharps injury protection — Requirements and test methods — Sharps containers, sections 5.3 and 5.4	The Sage Sharps Shuttle was tested via bench testing, in side by side comparison with the North American Rescue Sharps Shuttle, to demonstrate efficacy per ASTM 2132-01 (2008)e1 "Puncture of Materials used in Resistance of Materials containers for discarded used in containers for medical needles and other Sharps".	Yes
Sterile	No	No	Yes
Biocompatible materials	Not applicable per ISO 10993	Not applicable per ISO 10993	Yes
Use	Non-clinical setting	EMS, home health etc.	Yes
Instructions for Use	Yes	No	No
Materials	polypropylene	polypropylene	Yes