RHINOSYSTEMS
Creator of Naväge

510(k) Summary
(as required by section 807.92(c))

Submitted by:
RhinoSystems, Inc.
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Contact:
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Date First Submitted:
February 24, 2014
Date of Revised Submission:
June 25, 2014

Trade Name:
Naväge Nose Cleaner
Common Name:
Powered nasal irrigator
Classifications:
21 CFR 874.5550
Powered Nasal Irrigator
Product Code KMA
21 CFR 880.6740
Vacuum Powered Body Fluid Suction Apparatus
Product Code KDQ

Predicate Devices:
Respironics RinoFlow E.N.T. Nasal Wash System (K973875)
Ubimed Cleanoz Nasal Aspirator Kit

Device Description:
The Naväge Nose Cleaner ("Naväge") is a powered nasal irrigator intended for OTC use to wash and moisturize the nasal cavity. There are many nasal irrigation devices in commercial distribution in the US, and Naväge is substantially identical to those devices in terms of intended use and indications for use. It is similar in terms of mechanical functionality with the single exception that in addition to using positive pressure, Naväge simultaneously uses negative pressure (suction). That is, the device uses a combination of positive pressure (gravity) to introduce irrigant rinse into the nasal cavity, and negative pressure (powered suction) to aspirate the rinse out of the nasal cavity. The simultaneous use of positive and negative pressure makes it possible for the device to be self-contained so that after washing through the nasal cavity, the irrigant rinse can

flow into a removable collection tank attached to the device. This provides an improved nasal irrigation experience resulting from functional simplicity, superior ergonomics, and less mess than currently available devices.

Head pressure, the gravitational force resulting from the distance between the upper tank fill-line and the entrance nostril, is a positive pressure that decreases to zero as the irrigant runs out of the upper tank. Head pressure exerts its greatest influence at the beginning of the irrigation cycle when it helps *initiate* irrigant flow.

Negative pressure generated by a miniature, battery-powered pump serves two purposes. First, it evacuates air from the lower tank which allows the irrigant to flow into it. Second, it creates a small pressure differential that draws the irrigant out of the upper tank, through the nasal cavity, and into the lower tank, thereby making up for the loss of head pressure as the irrigant flows out of the upper tank. Naväge is designed so that the positive and negative pressures are essentially kept in balance which results in the user feeling little or no pressure within the nasal cavity during the cycle, thus providing a superior nasal irrigation experience. It also makes it possible for the effluent irrigant to be collected in the lower tank, resulting in a neater and more convenient overall experience.

Indications for Use:
The Naväge Nose Cleaner is intended to help relieve nasal and/or sinus congestion and stuffiness by washing and moisturizing the nasal cavity with a pressure-controlled stream of irrigant rinse.

Substantial Equivalence Statement:
The Naväge Nose Cleaner is substantially equivalent to the Respironics RinoFlow E.N.T. Nasal Wash System ("RinoFlow") cleared under K973875 as a 21 CFR 874.5550 *Powered Nasal Irrigator*. Naväge and RinoFlow are powered nasal irrigation devices that have the same intended use and indications for use, function in a similar manner, are constructed from the same basic materials, and share the same basic operational principles and technical characteristics. Naväge differs from RinoFlow in that in addition to irrigating, Naväge simultaneously *aspirates*.

With respect to aspiration, Naväge is substantially equivalent to the Ubimed Cleanoz Nasal Aspirator Kit ("Cleanoz") listed under 21 CFR 880.6740 *Vacuum Powered Body Fluid Suction Apparatus*. Therefore, in accordance with FDA guidance concerning how to identify a predicate when the subject device has two features not previously combined in a single predicate, both predicates are identified as substantially equivalent.

Performance testing data for flow rate of irrigant and pressure is submitted to demonstrate substantial equivalence with respect to operational characteristics. Both predicates are over-the-counter, and a comprehension study of the subject device's *Instructions for Use* is submitted to demonstrate substantial equivalence with respect to over-the-counter characteristics for consumer understandability and ease of use.

Substantial Equivalence Comparison Table:			
Attribute	***Subject Device*** **Naväge Nose Cleaner**	***Predicate Device*** **Rinoflow Micronized E.N.T. Wash System**	***Predicate Device*** **Cleanoz Nasal Aspirator Kit**
510(k) Number	K140542	K973875	N/A
Regulation	TBD	21 CFR 874.5550	21 CFR 880.6740
Name	TBD	*Powered Nasal Irrigator*	*Vacuum Powered Body Fluid Suction Apparatus*
Product Code	TBD	KMA	KDQ
Classification	TBD	Class I	Class II
Premarket Notification	TBD	Exempt	Exempt
Classification Description	TBD	*A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.*	*A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).*
Panel	TBD	Ear, Nose, and Throat	General Hospital and Personal Use
Intended use	The Naväge Nose Cleaner is intended to help relieve nasal and/or sinus congestion and stuffiness by washing and moisturizing the nasal cavity with a pressure-controlled	"Nasal and sinus irrigation and humidification of the upper respiratory tract"	From labeling: "To clean a stuffy or runny nose"

	stream of irrigant rinse.		
Indications for use	The Naväge Nose Cleaner is intended to help relieve nasal and/or sinus congestion and stuffiness by washing and moisturizing the nasal cavity with a pressure-controlled stream of irrigant rinse.	"To treat conditions and disorders of the upper respiratory tract where homeostasis of the nasal mucosa is disturbed, resulting in symptoms such as catarrh, and mucopurulent or crusty secretions. Such conditions and disorders include: • Rhinitis • Both acute and chronic sinusitis."	From labeling: 1. Cleanoz is designed for household use, only to aspirate baby's nasal secretions. 2. To improve the efficiency of Cleanoz, it is recommended to irrigate nasal passages with saline solution before aspirating secretions.
Intended Age Group	Age 12 and older	For adults and "children over three years of age"	Labeling specific to pediatric use
Anatomical sites	Nasal and sinus cavities	Nasal and sinus cavities	Nasal and sinus cavities
OTC or Rx	OTC	OTC	OTC
Human factors	Device is designed for personal use by consumers at home.	Device is designed for personal use by consumers at home.	Device is designed for personal use by consumers at home.
Power	3 volt DC	110 volt AC	3 volt DC
Design	Handheld, self-contained battery-powered unit is designed to irrigate the nasal cavity, and to remove and hold the irrigant effluent in a removable attached container. A small vacuum pump is used to accomplish this.	Same except that this device uses positive pressure only; is AC powered; and has a handheld nasal interface that is attached by tubes to a table-top control unit.	Same except that this device is used for aspiration only.
Performance (As specified)	Flow of 0.25 to 1.50 LPM; maximum suction of 23.5 inches water.	Flow of from 2 to 9.5 LPM; maximum pressure of 27.7 inches water.	Not published
Performance (As tested)	Flow of 0.27 to 1.31 LPM with	Flow of from 4 to 8 LPM; maximum	Maximum suction of 115 inches H2O.

	corresponding restrictions to flow of 0% to 75%; maximum suction of 21.4 inches H2O.	pressure of 18.1 inches H2O.	
Standards met	ISO 10993 parts 5 and 10 for biocompatibility; IEC60601 for EMC.	Same (presumed, since clearance issued)	Same (presumed)
Materials	The device uses common consumer product materials including plastic, an electrical pump, silicone, batteries, a power button, and wiring.	Same or similar	Same or similar
Biocompatibility	Biocompatible	Same (presumed; clearance issued)	Same (presumed)
Compatibility with environment and other devices	Compatible	Same (presumed, since clearance issued)	Same (presumed)
Sterility	Not provided sterile	Same	Same
Electrical safety	Complies with IEC-60601-1, including EMC requirements	Same (presumed, since clearance issued)	Same (presumed)
Mechanical safety	N/A	Same	Same
Chemical safety	N/A	Same	Same
Thermal safety	N/A	Same	Same
Radiation safety	N/A	Same	Same

Substantial Equivalence Conclusion:
The Naväge Nose Cleaner shares the same or similar intended use, indications for use, intended users, device operation, overall technical and functional capabilities, and technological characteristics and performance with RinoFlow as a *Powered Nasal Irrigator* and with Cleanoz as a *Vacuum Powered Body Fluid Suction Apparatus.* Therefore it is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 27, 2014

RhinoSystems, Inc.
c/o Mr. Martin R. Hoke
President
5399 Lancaster Drive, Unit 6
Brooklyn Heights, OH 44131

Re: K140542
Trade/Device Name: Navage Nose Cleaner
Regulation Number: 21 CFR 874.5550
Regulation Name: Powered Nasal Irrigator
Regulatory Class: Class II
Product Code: KMA, KDQ
Dated: May 22, 2014
Received: May 27, 2014

Dear Mr. Hoke:

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,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140542

Device Name
RhinoSystems, Inc. Navägе Nose Cleaner

Indications for Use *(Describe)*
The Navägе Nose Cleaner is intended to help relieve nasal and/or sinus congestion and stuffiness by washing and moisturizing the nasal cavity with a pressure-controlled stream of irrigant rinse.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Vasant G. Malshet -S

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