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

Submitted by:
RhinoSystems, Inc.
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Contact:
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Email: mrhoke@cox.net

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. Navage 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 Navage 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 Navage 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. Navage 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. Navage differs from RinoFlow in that in addition to irrigating, Navage simultaneously aspirates.

With respect to aspiration, Navage 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:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Naväge Nose Cleaner</td>
<td>Rinoflow Micronized E.N.T. Wash System</td>
<td>Cleanoz Nasal Aspirator Kit</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K140542</td>
<td>K973875</td>
<td>N/A</td>
</tr>
<tr>
<td>Regulation</td>
<td>TBD</td>
<td>21 CFR 874.5550</td>
<td>21 CFR 880.6740</td>
</tr>
<tr>
<td>Name</td>
<td>TBD</td>
<td>Powered Nasal Irrigator</td>
<td>Vacuum Powered Body Fluid Suction Apparatus</td>
</tr>
<tr>
<td>Product Code</td>
<td>TBD</td>
<td>KMA</td>
<td>KDQ</td>
</tr>
<tr>
<td>Classification</td>
<td>TBD</td>
<td>Class I</td>
<td>Class II</td>
</tr>
<tr>
<td>Premarket</td>
<td>TBD</td>
<td>Exempt</td>
<td>Exempt</td>
</tr>
<tr>
<td>Notification</td>
<td>TBD</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td><strong>TBD</strong></td>
<td><strong>TBD</strong></td>
<td><strong>TBD</strong></td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panel</td>
<td>TBD</td>
<td>Ear, Nose, and Throat</td>
<td>General Hospital and Personal Use</td>
</tr>
<tr>
<td>Intended use</td>
<td>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</td>
<td>“Nasal and sinus irrigation and humidification of the upper respiratory tract”</td>
<td>From labeling: “To clean a stuffy or runny nose”</td>
</tr>
</tbody>
</table>
| **Indications for use** | 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. |

<p>| <strong>Intended Age Group</strong> | Age 12 and older | For adults and &quot;children over three years of age&quot; | Labeling specific to pediatric use |
| <strong>Anatomical sites</strong> | Nasal and sinus cavities | Nasal and sinus cavities | Nasal and sinus cavities |
| <strong>OTC or Rx</strong> | OTC | OTC | OTC |
| <strong>Human factors</strong> | 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. |
| <strong>Power</strong> | 3 volt DC | 110 volt AC | 3 volt DC |
| <strong>Design</strong> | 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. |
| <strong>Performance (As specified)</strong> | 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 |
| <strong>Performance (As tested)</strong> | Flow of 0.27 to 1.31 LPM with | Flow of from 4 to 8 LPM; maximum | Maximum suction of 115 inches H2O. |</p>
<table>
<thead>
<tr>
<th>Standards met</th>
<th>ISO 10993 parts 5 and 10 for biocompatibility; IEC60601 for EMC.</th>
<th>Same (presumed, since clearance issued)</th>
<th>Same (presumed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td>The device uses common consumer product materials including plastic, an electrical pump, silicone, batteries, a power button, and wiring.</td>
<td>Same or similar</td>
<td>Same or similar</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Biocompatible</td>
<td>Same (presumed; clearance issued)</td>
<td>Same (presumed)</td>
</tr>
<tr>
<td>Compatibility with environment and other devices</td>
<td>Compatible</td>
<td>Same (presumed, since clearance issued)</td>
<td>Same (presumed)</td>
</tr>
<tr>
<td>Sterility</td>
<td>Not provided sterile</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Electrical safety</td>
<td>Complies with IEC-60601-1, including EMC requirements</td>
<td>Same (presumed, since clearance issued)</td>
<td>Same (presumed)</td>
</tr>
<tr>
<td>Mechanical safety</td>
<td>N/A</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Chemical safety</td>
<td>N/A</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Thermal safety</td>
<td>N/A</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Radiation safety</td>
<td>N/A</td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>

Substantial Equivalence Conclusion:
The Navágé 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.
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" (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 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
Naväge Nasal Irrigator

Indications for Use

The Navige 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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