

K473875

SECTION 12

SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 26 1998



RESPIRONICS INC.

1001 Murry Ridge Drive, Murrysville, PA 15668

October 9, 1997

Official Contact	Francis X. Dobscha Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Drive Murrysville, PA 15668
Classification Name	21 CFR 874.5550, 77 KMA
Common/Usual Name	Powered Nasal Irrigator
Proprietary Name	RinoFlow Micronized E.N.T. Wash System
Predicate Devices	Puls-ator Irrigator Lavage - K821481 Ethicare P.O. Box 5027 Fort Lauderdale, FL 33310

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the RinoFlow Micronized E.N.T. Wash System is substantially equivalent to the Ethicare Puls-ator Irrigator Lavage (K821481), which is used to irrigate the nasal and sinus passages and humidify the upper respiratory tract.

Testing was performed to demonstrate that the performance of the RinoFlow Micronized E.N.T. Wash System in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the RinoFlow Micronized E.N.T. Wash System were verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The RinoFlow Micronized E.N.T. Wash System was tested and found compliant with the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

General Technical Description

Intended Use/Indications for Use

RinoFlow Micronized E.N.T. Wash System aerosolizes solutions intended for nasal and sinus irrigation and humidification of the upper respiratory tract. RinoFlow is used 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 (as a symptom of colds, allergies, etc.)
- Both Acute and Chronic Sinusitis

RinoFlow Micronized E.N.T. Wash System should be used with a physiological saline solution. "Tap" water is not recommended.

Contraindications

The following pre-existing conditions contraindicate the use of the RinoFlow System:

- Operations to the tympanum (eardrum), including plastic operations on the tympanum
- Other pathologies of the tympanic area

- Injuries or recent surgery that may have fractured or disturbed the cribriform plate

Patient Population

Adults and pediatrics (age ≥ 3).

Environment of Use

Home and doctor's office.

Manufacturer

The RinoFlow Micronized E.N.T. Wash System is manufactured by Mefar (Italy) and distributed in the United States by Respironics, Inc.

Summary of the Device Description

The RinoFlow Micronized E.N.T. Wash System provides aerosol irrigation with positive pressure. The device has two settings that facilitate a two-phase procedure for nasal irrigation and upper respiratory tract humidification. Phase One washes the nasal cavity and nasopharynx by hydrating and softening the mucus with a stream of large-particle aerosol, causing drainage to occur. Phase Two applies the aerosol stream with higher velocity that reaches the paranasal sinuses.

Technical Description

The RinoFlow E.N.T. Wash System consists of a Micronizer-Chamber connected by a length of tubing to a lubricant-free, sealed piston compressor. The compressor incorporates a reciprocating power pump design.

The Micronizer-Chamber, made of synthetic, washable polycarbonate material, is in four essential parts: the body, the inner shell, the outer shell, and the baffle. Tubing is connected at the bottom of the body. At the top of the body is an air injector covered by a baffle. The bell-shaped inner shell surrounds the air injector and baffle and tapers to an outlet at the top for the aerosol stream to exit. The rim at the bottom of the shell fits in a groove at the top of the body. The space inside the inner shell forms the inner chamber, where the liquid is micronized. The outer shell fits over the body, surrounding the inner shell and its contents. The outer shell is cylindrical and tapers to an outlet at the top. The outer shell can be rotated to two different positions, gliding vertically over the body. In the first position, the outer shell's outlet is vertically aligned slightly above that of the inner shell. The space between

the outer shell and the inner shell forms the outer chamber, where the drainage is collected. This chamber is sealed at the bottom by an O-ring. The space between the very tops of the inner and outer shells forms an opening for the drainage to descend into the outer chamber during Phase 1. Four holes around the rim at the top of the outer shell provide the primary means for excess nasal drainage to enter the outer chamber. These holes also provide an outlet for patient exhalation.

When rotated to the second position, the outer shell lowers so its outlet meets that of the inner shell, joining the holes to create a single outlet. This configuration increases the velocity of the aerosol stream. The outer chamber is unaffected by this change in shell configuration, and any residual drainage will continue to enter the chamber via the four holes along its rim.

Principles of Operation

The Micronizer-Chamber is set for irrigation of the nasal cavity by rotating the outer shell to the first setting as indicated. Liquid is placed into the inner chamber of the Micronizer-Chamber. The outlet of the outer shell is placed in the opening of one nostril and held in that position. When the power button is pressed on, the compressor pressurizes the liquid via the air injector, creating a large-particle aerosol stream that is delivered through the outlet into the nasal cavity and nasopharynx. The irrigation of the mucous membranes softens and thins the mucus, facilitating its drainage. The drainage enters the space between the very tops of the inner and outer shells and descends into the outer chamber. Any drainage that does not enter the opening between the inner and outer shells is guided into the rim at the top of the outer shell. From there, the drainage descends through the four rim holes into the outer chamber. Because of the delivery pressure of the micronized wash solution, the nasal drainage cannot enter the inner chamber and mix with the washing fluid. The pressure generated by the patient's exhalation is released through the four holes on the outer shell. The procedure is repeated with the other nostril.

Once the wash is complete and the Micronizer-Chamber has been rinsed, the Micronizer-Chamber can be set for irrigation of the paranasal sinuses by rotating the outer shell to the second setting as indicated. This setting increases the velocity of the aerosol stream to reach the paranasal sinuses. The outlet of the outer shell is placed lightly against the opening of one nostril and held in that position. During

treatment, the patient closes the contralateral nostril and periodically swallows and holds his or her breath for a brief period. Any drainage that leaks from the nostril will continue to enter the chamber via the four holes along its rim. The pressure generated by the patient's exhalation is released through the four holes on the outer shell. The procedure is repeated with the other nostril.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1998

Francis X. Dobscha
Manager, Regulatory Affairs
Respironics
1001 Murry Ridge Drive
Murrysville, Pennsylvania 15668-8550

Re: K973875
Respironics RinoFlow Micronized E.N.T. Wash System
Dated: January 5, 1998
Received: January 7, 1998
Regulatory class: I
21 CFR 874.5550/Procode: 77 KMA

Dear Mr. Dobscha:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973875

Device Name: RinoFlow Micronized E.N.T. Wash System

Intended Use/Indications for Use

The RinoFlow Micronized E.N.T. Wash System aerosolizes solutions intended for nasal and sinus irrigation and humidification of the upper respiratory tract. RinoFlow is used 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 (as a symptom of colds, allergies, etc.)
- Both Acute and Chronic Sinusitis

RinoFlow Micronized E.N.T. Wash System should be used with a physiological saline solution. "Tap" water is not recommended.

RinoFlow Micronized E.N.T. Wash System is intended to be used by adults and pediatrics (age ≥3) in the home or doctor's office, and is available over-the-counter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Ferguson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K973875

Prescription Use _____

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)