K091853

SEP 21 2009

510(K) Summary

Submitter Information

Submitter Name:	nSpire Health, Inc. 1830 Lefthand Circle Longmont, CO 80501
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Date Prepared:	April 2009

Device Category

Regulation No.:	21 CFR 868.1850
Product Code:	BZK
Regulatory Class:	II
Trade Name:	Wright/Haloscale Respirometer
Common Name:	Respirometer
Classification name:	Spirometer, monitoring (w/wo alarm)

Equivalent legally-marketed devices.

Boehringer Laboratories Adult Spirometer #8800

Description

The Respirometer is a mechanically driven dial, where the dial indicates gas volume passed, and the mechanism is driven by the kinetic energy in the flowing gas. The device measures expirate gas flow and measurements are unaffected by inspirate gas flow. It has an on/off button to lock the pointer and a reset button to return the pointer to zero when it approaches full scale

Intended Use

The intended use of the Wright/Haloscale Respirometer is the measurement and monitoring of the level of lung ventilation achieved by intensive care patients, during anesthesia and post operative recovery.

It measures expired volumes and thus indicates whether adequate ventilation is being achieved, whether in open or closed circuit or spontaneously breathing or mechanically ventilated patients.

Technological Characteristics

Accuracy	Tidal Volumes:	± 3% for minute volumes exceeding 5 LPM ± 4% for minute volumes exceeding 4 LPM
	Continuous Flow:	± 2% @ 16 LPM ± 5% to + 10% @ 60 LPM
Sensitivity	Starts volume registration at not more than 2.5 LPM	
Resistance	Proportional to square of the flow rate and not more than 2cm H_2O @ 100 LPM	
Dead Space	22 ml	

Permissible Gases	All respirable gases
Maximum Temperature	55°C (131°F)
Maximum internal to external pressure	30cm H_2O
Maximum Leakage	60ml/min at 30cm H_2O (to ASTM F1208-89)
Maximum Recommended Flow Rate	60 LPM (300 LPM continuous flow for short periods)

Conclusion

The nSpire Respirometer has the same intended use and indications, principle of operation, technological characteristics, and is substantially equivalent in safety and effectiveness to the marketed predicate device with respect to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Ms. Kimberly Stark
Director of Global Quality and Regulatory Affairs
NSpire Health, Incorporated
1830 Lefthand Circle
Longmont, Colorado 80501

Re: K091853
Trade/Device Name: Wright/Haloscale Respirometer
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK
Dated: June 22, 2009
Received: June 23, 2009

Dear Ms. Stark:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Wright/Haloscale Respirometer

Indications for Use:

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It measures expired volumes and thus indicates whether adequate ventilation is being achieved, whether in open or closed circuit or spontaneously breathing or mechanically ventilated patients.

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091853

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)