RxPeakFlow Meter

K101380

510(k) Summary
Traditional 510(k) Premarket Notification
Summary of Safety and Effectiveness

SEP 13 2010

Submitter Information	Noble Marketing Jeff Baker President & CEO 100 East Pine Street, Suite 305 Orlando, FL 32801
Contact Person	Laura Lyons Sr. Regulatory Consultant 317-569-9500 317-569-9520 (fax)
Date	May 14, 2010
Trade Name	RxPeakFlow
Common Name	Meter, Peak Flow
Classification Name	BZH
Classification Number	21 CFR 868.1860

Predicate Devices				
	MicroPeak	K030586	BZH	868.1860

Device Description	The RxPeakFlow is a device used to measure the peak expiratory flow of a patient. The Peak Expiratory Flow Rate is a recognized lung function value that is helpful in monitoring of respiratory conditions such as asthma. The device can be used anywhere the patient needs to measure their peak expiratory flow rate. It is a single patient use device intended for use for children to adults.
Intended Use	The RxPeakFlow is a single patient use device to measure a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma. The device can be used anywhere the patient needs to measure their peak expiratory flow rate. It is a single patient use device intended for use for children to adults
Comparison to Predicate Devices	The RxPeakFlow is similar to the predicate in intended use, materials, measuring principle and performance.

Device Comparisons	*RxPeakFlow* .	*MicroPeak*
Indicated use	Measures a patient's peak expiratory flow rate.	Measures a patient's peak expiratory flow rate.
Target Population	Children to Adults	Patients requiring the measurement of peak expiratory flow.
Environment of use	Anywhere a patient may require the measurement of peak expiratory peak flow.	Anywhere a patient may require the measurement of peak expiratory peak flow.
Design	Single Patient Use	Single Patient Use
Measuring Principle	Tension Spring Piston/Pointer	Tension Spring Piston/Pointer
Performance		
Range	60-800 L/Min	60-900 L/Min
Accuracy	+/- 10%	+/- 10%
Intra device Precision	+/- 5%	+/- 5%
Inter device Precision	+/-5%	+/- 5%
Materials	Housing- ABS	Housing- ABS
Differences	Small difference in measurement range.	

Technological Characteristics The RxPeakFlow uses a tension spring piston/pointer measuring principle.

Performance of Non-Clinical The RxPeakFlow has been tested for performance through bench testing. The device passed all testing and met the criteria for range, accuracy and precision required by the American Thoracic Society's Standardization of Spirometry, specifically the ATS 26 flow-time waveform testing.

Conclusion The RxPeakFlow is substantially equivalent to a legally marketed predicate device and meets recommended ATS standards.

End of document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Noble Marketing
C/O Ms. Laura Lyons
Anson Group, LLC
11460 N. Meridian Street, Suite 150
Carmel, Indiana 46032

SEP 13 2010

Re: K101380
Trade/Device Name: RxPeakFlow
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: August 30, 2010
Received: August 30, 2010

Dear Ms. Lyons:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

K101380

510(k) Number: Pending

SEP 13 2010

Device Name: RxPeakFlow

Indications For Use:

The RxPeakFlow is a single patient use device to measure a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma. The device can be used anywhere the patient needs to measure their peak expiratory flow rate. It is a single patient use device intended for use for children to adults.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(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)

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L. Schultz

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

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