# RxPeakFlow Meter

## 510(k) Summary

**Traditional 510(k) Premarket Notification**

**Summary of Safety and Effectiveness**

| Submitter Information | Noble Marketing  
|---|---|
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Orlando, FL 32801 | SEP 13 2010 |
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| 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

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

### 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.
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” (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,

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

510(k) Number: Pending

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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[Signature]

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

510(k) Number: K101380