



Food and Drug Administration  
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May 27, 2016

PARI Respiratory Equipment, Inc.  
Michael Judge  
VP, Operations and Regulatory Affairs  
2412 Pari Way  
Midlothian, Virginia 23112

Re: K150044  
Trade/Device Name: PARI O-PEP  
Regulation Number: 21 CFR 868.5690  
Regulation Name: Incentive Spirometer  
Regulatory Class: Class II  
Product Code: BWF  
Dated: Undated  
Received: April 27, 2016

Dear Michael Judge:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Erin I. Keith M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
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Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** K150044

**Device Name:** PARI O-PEP

### Indications for Use:

The PARI O-PEP is intended for use as a Positive Expiratory Pressure Device, and is designed to help patients improve secretion clearance. The PARI O-PEP is intended for adult and pediatric patients ages 5 and older, for use in home, hospital, and sub-acute institutions.

Prescription Use XXX  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page \_\_ of \_\_  
(Posted November 13, 2003)

**PARI O-PEP Oscillating Positive Expiratory Pressure Device  
510(k) Submission  
510(k) Summary**

**Submitter Information**

Name: PARI Respiratory Equipment, Inc.  
Address: 2412 PARI Way  
Midlothian, VA 23112  
Phone Number: 804-253-7274 x269  
Fax Number: 804-253-0260  
Contact Name: Michael Judge  
Date Prepared: May 26, 2016

**Device Name**

Common Name: O-PEP (Oscillating Positive Expiratory Pressure) Device  
Trade Name: PARI O-PEP  
Classification Name: Spirometer, Therapeutic (Incentive), 21 CFR 868.5690, Product Code BWF

**Legally Marketed Predicate Device(s)**

<b>Manufacturer</b>	<b>Device</b>	<b>510(k) Number</b>
Aptalis Pharma	Flutter D	K972859 (primary)
Bradstreet Clinical Research Assoc., Inc.	Flutter	K946083

**Device Description**

The PARI O-PEP (Oscillating Positive Expiratory Pressure) is a small, single patient use, reusable oscillating PEP therapy device. The PARI O-PEP is a respiratory therapy device designed for temporary application to mobilize secretions or mucous in the lower respiratory tract, strengthen the respiratory tract and alleviate shortness of breath. The patient exhales repeatedly into the device against a movable ball, causing a vibration that is transmitted to the lungs. This causes the deeper respiratory tract to open. By doing this, secretions are mobilized and able to move up the airways. The device is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments.

**Medical Condition Treated**

The PARI O-PEP is intended to help patients with respiratory conditions clear mucus and secretions from their airways.

**Indications For Use**

The PARI O-PEP is intended for use as a Positive Expiratory Pressure Device, and is designed to help patients improve secretion clearance. The PARI O-PEP is intended for adult and pediatric patients ages 5 and older, for use in home, hospital, and sub-acute institutions.

**Technological Characteristics Compared to Predicate Device**

The PARI O-PEP is substantially equivalent to the predicate devices Flutter and Flutter D. Table 1 below is a summary of the comparison.

Table 1.

<b>Features</b>	<b>Proposed PARI O-PEP</b>	<b>Primary Predicate Flutter D K972859</b>	<b>Secondary Predicate Flutter K946083</b>
<b>Indications for use</b>	The PARI O-PEP is intended for use as a Positive Expiratory Pressure Device, and is designed to help patients improve secretion	The efficacy of the Flutter D as a mucus clearance device for cystic fibrosis patients is based on its ability to 1) vibrate the airways (which loosens	The Flutter provides positive expiratory pressure (PEP) therapy for patients with mucus-producing respiratory conditions,

	clearance. The PARI O-PEP is intended for adult and pediatric patients ages 5 and older, for use in home, hospital, and sub-acute institutions	mucus from the airway walls), 2) intermittently increase endobronchial pressure (to maintain the patency of airways during exhalation, so that mucus does not become trapped as it moves up the airways), and 3) accelerate expiratory airflow (to facilitate the upward movement of mucus through the airways so that it can be more easily coughed out). Flutter D may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for Positive Expiratory Pressure (PEP) Therapy.	including: Atelectasis, Bronchitis, Bronchiectasis, Cystic Fibrosis, Chronic Obstructive Pulmonary Disease (COPD), Asthma or other conditions producing retained secretions.
<b>Product Code and Regulation No.</b>	BWF, 21 CFR 868.5690	BYI, 21 CFR 868.5665	BYI, 21 CFR 868.5665
<b>Prescription Use</b>	Rx Only	Rx Only	Rx Only
<b>Environment of Use</b>	Home, Hospital, Sub-acute Institutions	Not indicated	Not indicated
<b>Patient Population</b>	Pediatric Adult	Patients with mucus-producing respiratory conditions – age restrictions not specified	Patients with mucus-producing respiratory conditions – age restrictions not specified
<b>Contraindications</b>	Pneumothorax, right ventricular insufficiency, coughing up blood and tuberculosis.	Pneumothorax, overt right-sided heart failure.	Pneumothorax, overt right-sided heart failure.
<b>Software driven</b>	No	No	No
<b>Materials in patient contact</b>	Rigid injection-molded polymer – POM.	Rigid injection-molded polymer	Rigid injection-molded polymer
<b>Oscillation frequency</b>	Oscillation frequency of PARI O-PEP device is comparable to predicate Flutter across a range of flow rates between 5 and 30 LPM.		
<b>Expiratory resistance</b>	Pressure level of PARI O-PEP device is comparable to predicate Flutter across a range of flow rates between 5 and 30 LPM.		
<b>Cleaning and disinfection</b>	Cleaning only, soap and water.	N/A	Cleaning only, soap and water.

### **Discussion of Differences**

The design and intended use of the subject and predicate devices are similar, since both sets are oscillating resistance devices for prescription use, and aid patients with mucus secretion through the airways via Positive Expiratory Pressure. Product codes and regulation numbers for the subject device and predicate devices differ; however, devices under both regulations are used to transmit vibrations through the patient's chest wall to aid in freeing mucus and improving ventilation. Performance testing demonstrates that the PARI O-PEP and predicate Flutter D devices were tested to compare oscillation frequency and expiratory resistance. Results demonstrate that the PARI O-PEP device produces comparable oscillation frequencies across a range of flow rates and pressure ranges.

### **Non-Clinical Test Summary**

PARI O- PEP was tested to compare performance to the predicate Flutter device and satisfy applicable guidance, including:

- Expiratory resistance: PARI O-PEP expiratory pressure level was compared to the predicate Flutter device across a range of flow rates between 5 and 30 LPM and angular positions of 0 and 30 degrees, and was found to be substantially equivalent to the predicate device for all variables.
- Oscillating frequency: PARI O-PEP oscillating frequency was compared to the predicate Flutter device across a range of flows between 5 and 30 LPM and angular positions of 0 and 30 degrees, and was found to be substantially equivalent to the predicate device for all variables.
- Biocompatibility: Testing demonstrates that the subject device meets requirements in accordance with:
  - ISO 10993-1: Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
  - ISO 10993-5: Biological Evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- Cleaning efficacy validation: Testing demonstrates that the subject device meets requirements for cleaning of a reusable medical device in accordance with recognized guidelines, including:
  - AAMI TIR No. 30, 2011: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices

### **Clinical Performance Summary**

Clinical testing was not completed/is not required to show substantial equivalence.

### **Conclusion**

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicates have been found to be substantially equivalent.