K090829

PARI PEP S Positive Expiratory Pressure Device
510(k) Submission
510(k) Summary

JUL 21 2009

Submitter Information

Name:	PARI Respiratory Eqiupment, Inc.
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Date Prepared:	March 6, 2009

Device Name

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

Legally Marketed Predicate Device(s)

Manufacturer	Device	510(k) Number
PARI Respiratory Equipment, Inc.	PARI PEP	K972042
Smiths Medical, Inc.	TheraPEP	K983467

Device Description

The PARI PEP S is a small, single patient use, reusable PEP therapy device for use as a stand alone PEP device or for use with aerosol drug delivery. The device is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments.

Indications For Use

The PARI PEP S is intended for use as a Positive Expiratory Pressure Device, and is designed to help patients exercise their lungs properly and improve secretion clearance. The PARI PEP S may be used by itself or in conjunction with aerosol drug therapy. The PARI PEP S is intended for adult and pediatric patients, for use in home, hospital, and sub-acute institutions.

Technological Characteristics Compared to Predicate Device

The PARI PEP S, PARI PEP and TheraPEP are all fixed orifice, positive expiratory pressure devices where a choice of orifices are provided allowing a clinician to select the appropriate settings to accommodate a patient breathing pattern. All devices incorporate a one way valve to allow low resistance inhalation and exhalation through the selected restrictive orifice. All three devices include a pressure monitoring port to allow user or clinician monitoring of the expiratory pressure. PARI PEP S, PARI PEP and TheraPEP may all be used as stand alone devices or may be used in conjunction with aerosol therapy.

The PARI PEP S uses materials identical to the PARI PEP system.

Non-Clinical Test Summary

PARI PEP S was tested to compare performance to the predicate PARI PEP device, including:

- Expiratory resistance: PARI PEP S is comparable to the predicate devices.
- Inspiratory Resistance: PARI PEP S is comparable to the predicate devices

Clinical Performance Summary

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

Conclusions from Testing

PARI PEP S meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Judge
Director of Quality Assurance and Regulatory Affairs
PARI Respiratory Equipment, Incorporated
2943 Oak Lake Boulevard
Midlothian, Virginia 23112

JUL 21 2009

Re: K090829
Trade/Device Name: PARI PEP S
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: July 1, 2009
Received: July 2, 2009

Dear Mr. 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.

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,

Susan Runner, D.D.S., M.A.
Acting 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 (if known): N/A

Device Name: PARI PEP S

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090829