NOV 10 1999

510(k) Summary

Submitter:

DHD Healthcare Corporation
125 Rasbach Street
Canastota, NY 13032

Contact: Larry Weinstein, Technology Manager
Phone: 315-697-2221
Fax: 315-697-5191

Device Name:

Product Code Name:	Roadrunner
Trade name:	To Be Determined
Common Name:	Positive Expiratory Pressure (PEP) Device
Classification Name:	Incentive Spirometer – 868.5690

Predicate Devices:

TheraPEP® [(1)] :	Flutter® [(2)] : K946083
K944900, K962749, K983467	K940986, K946083
DHD Healthcare	Scandipharm Incorporated
125 Rasbach Street	22 Inverness Center Pkwy
Canastota NY 13032	Birmingham, Alabama 35242

Device Description:

The DHD Roadrunner is indicated for use as a single patient use, hand held secretion clearance and lung expansion device that creates vibrating positive expiratory pressure when a patient exhales through the device.

Intended Use:

Positive Expiratory Pressure (PEP) Therapy

Technological Characteristics Compared to Predicate:

Roadrunner, TheraPEP and Flutter are all PEP devices providing positive expiratory pressure. Roadrunner and Flutter offer the added vibration feature during exhalation. All three devices improve secretion clearance, reduce the need for postural drainage, facilitate the opening of airways, and prevent or reverse atelectasis. Roadrunner offers some additional features over Flutter by allowing inhalation without removing the device from the patient's mouth, allowing the device to perform in any spatial orientation, accommodating patients with very low flowrates and allowing patients to adjust frequency and pressure with the use of an external knob.

Summary of Studies:

The bench & human testing compares Roadrunner to Flutter and against its own performance specifications. Roadrunner is compared to DHD's TheraPEP®[(2)] device as a marketed PEP device with similar claims. In each test or comparison, the

Roadrunner Device was shown to be substantially equivalent to the predicates and met its specifications.

Conclusion Drawn from Studies

For the indications for use, the DHD Roadrunner performs substantially equivalent to the predicate devices, Flutter® and TheraPEP®. In the opinion of DHD, it is substantially equivalent to the predicate devices and does not adversely affect safety and effectiveness compared to the predicate devices.

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(1) TheraPEP® is a registered trademark of DHD Healthcare Corporation.
(2) Flutter® is a registered trademark of VarioRaw Percutive, a Scandipharm Company.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. Larry Weinstein
DHD Healthcare Corporation
One Madison Street
Wampsville, NY 13163

Re: K991561
Roadrunner, PEP Therapy Device
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: August 12, 1999
Received: August 13, 1999

Dear Mr. Weinstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991561

Device Name: Roadrunner

Indications For Use:

1 - Purpose:
The DHD Roadrunner is indicated for use as a Positive Expiratory Pressure (PEP) Device.

2 - Claims:
- The use of DHD Roadrunner improves clearance of secretions
- The use of DHD Roadrunner may reduce the need for postural drainage
- DHD Roadrunner facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems
- The DHD Roadrunner may be used to prevent or reverse atelectasis

3 - Target Patient Population
Patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy.

4 - Intended Environment For Use
- Labeling reflects the statement: "Federal (USA) Law restricts this device to sale by or on the order of a physician."
- May be used in hospital as well as the home after a period of training.

5 – Legally Marketed Predicate Device(s):
- DHD TheraPEP (K944900, K962749, K983467)
- Scandipharm Flutter (K940986, K946083)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991561

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)