K971285

JUN 5 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: August 1, 1997

Device Name: Flutter®D Mucus Clearance Device

Classification Name: Powered Percussors

Manufacturer: Atrion Medical Products Inc. (formerly Ryder International Corp.) for VarioRaw SA, a subsidiary of Scandipharm, Inc., Birmingham, Alabama.

Contact:
Patricia Bradstreet (Consultant to VarioRaw SA)
Bradstreet Clinical Research Associates, Inc.
1588 Route 130 North, Suite C-2
North Brunswick, NJ 08902
(732) 821-0800

Predicate: Flutter® Mucus Clearance Device which was cleared for market under K940986 and K946083.

Device Description: The Flutter®D is a small hand held device consisting of a hardened plastic mouthpiece at one end, a plastic cover with an opening at the other end, and a valve on the inside created by a high density steel ball resting in a plastic circular cone.

Intended Use and Technological Characteristics: The Flutter®D is to be used to assist in the clearance of excessive secretions from the lungs of patients with cystic fibrosis, bronchitis, bronchiectasis and other diseases which cause the lungs to produce excessive amounts of mucus. It may also be used in conjunction with a medical need for positive expiratory pressure (PEP) therapy.

The Flutter®D is an expiration resisting device that delivers internal vibrations to patients' airways. The moveable ball inside the Flutter®D opposes the patient's exhaled air, creating a resistance to his expiration due to the weight of the steel ball.

The vibrations cause an oscillation effect down in the smallest airway passages within the lungs. With repeated vibrations, mucus secretions are mobilized from deep within the lungs to the throat where they can be huffed up and expectorated.

Clinical and Non-Clinical Similarities and Differences:

The original Flutter® has been shown to be effective in clearing mucus from patients with cystic fibrosis, bronchitis, bronchiectasis and other diseases in which mucus accumulates in the lungs and is effective in dislodging mucus from airway walls and thus facilitating its clearance by subsequent voluntary cough. It may also be useful in conjunction with a medical need for positive expiratory pressure (PEP) therapy.

Although no clinical trials have been performed on the Flutter®D disposable device, the modifications in design and material were minor and did not significantly affect the oscillation patterns generated by a continuous air flow; therefore, Flutter®D will be as effective as the original Flutter® in dislodging mucus from airway walls and facilitating mucus clearance and in conjunction with a medical need for positive expiratory pressure (PEP) therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 5 1998

Ms. Patricia Bradstreet
Bradstreet Clinical Research Associates, Inc.
1588 Route 130 North, Suite C-2
North Brunswick, NJ 08902

Re: K972859
Flutter-D Mucus Clearance Device
Regulatory Class: II (two)
Product Code: 73 BYI
Dated: March 16, 1998
Received: March 17, 1998

Dear Ms. Bradstreet:

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(k) Number (if known): _____

Device Name: Flutter®D Mucus Clearance Device

Indications for Use:

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 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.

(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 K972859

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21CFR 801.109)

(Optional Format 1-2-96)