K992038

SEP 9 1999

510(k) SUMMARY

Ferraris Medical Inc. PocketSpacer

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Mr. David R. Malys
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Date Prepared:
June 16, 1999

Name of Device and Name/Address of Sponsor

Ferraris Medical Inc. PocketSpacer

Mr. David R. Malys
President
Ferraris Medical Inc.
9681 Wagner Road
Post Office Box 344
Holland, New York 14080

Common or Usual Name
Spacer; Aerosol Holding Chamber

Classification Name
Accessory to a Nebulizer

Predicate Devices
Respiratory Delivery System's MicroChamber

Intended Use

The PocketSpacer is intended to assist with the delivery of aerosolized medications when used in conjunction with commercialized MDI canisters with the associated activator elbow. The spacer device is indicated to assist in the treatment of patients with lung disease such as, but not limited to, asthma, emphysema, chronic bronchitis, and cystic fibrosis.

Technological Characteristics and Substantial Equivalence

The PocketSpacer is a cylindrical tube, approximately 10 cm long by 4.5 cm wide, and accepts the MDI manufacturer's mouthpiece. The MDI receptacle has an orifice of size and shape similar to the MDI mouthpiece. The device is designed to prevent off-center actuations. An open mesh with varying size circular orifices, but no valve, is in the round mouthpiece. The mesh with concentrically placed circular orifices removes the throat dose by permitting only respirable particles to be inhaled by the user. The PocketSpacer is substantially equivalent to the MicroChamber.

Performance Data

Ferraris performed the Cascade Impactor Test comparing the PocketSpacer with the MicroChamber and an MDI actuator without a spacer device for four categories of drugs. The PocketSpacer performed comparably to the MicroChamber in terms of total dose, respirable dose, and mass median aerodynamic diameter. In addition, the PocketSpacer device with a commercial MDI provided finer, more highly respirable aerosols compared to the aerosols generated with the MDIs alone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Mr. Jonathan S. Kahan
Ferraris Medical, Inc.
c/o Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-5600

Re: K992038
PocketSpacer Metered Dose Inhaler Spacer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: June 16, 1999
Received: June 16, 1999

Dear Mr. Kahan:

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,

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

510(k) Number (if known): K992038

Device Name: **Ferraris Medical Inc.'s PocketSpacer**

Indications for Use:

The PocketSpacer is intended to assist with the delivery of aerosolized medications when used in conjunction with commercialized MDI canisters with the associated activator elbow. The spacer device is indicated to assist in the treatment of patients with lung disease such as, but not limited to, asthma, emphysema, chronic bronchitis, and cystic fibrosis.

(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 K992038

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)