DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

Ms. Jean Wallace
DHD Healthcare, Diemolding Corporation
One Madison Street
Wampsville, NY 13163

Re: K973532
Stealth, Metered Dose Inhaler (MDI) Spacer
without Integral Actuator
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: January 13, 1998
Received: January 15, 1998

Dear Ms. Wallace:

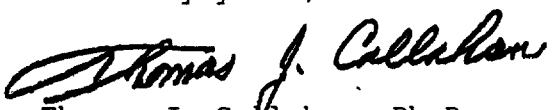
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, 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): K973532

Device Name: Stealth

Indications For Use:

1 - Purpose:

The DHD Stealth Metered Dose Inhaler (MDI) Spacer (Without Integral Actuator) assists with the delivery of aerosolized medications when used in conjunction with commercially available Metered Dose Inhaler (MDI) canisters with their associated actuator elbows. In addition, for convenience, the MDI canister/elbow, may be stored inside of the Stealth when not in use (the spacer acts as the MDI canister/elbow holding chamber).

2 - Claims:

2.1 Use of the Stealth Spacer, without integral actuator, assists with the delivery of aerosolized medications from Metered Dose Inhaler (MDI) canisters.

2.2 Use of the Stealth Spacer reduces patient coordination and technique oriented problems associated with MDI drug delivery.

3 - Target Patient Population:

Patients capable of following directions for hand held use of Metered Dose Inhaler (MDI) Spacer therapy as determined by a physician.

4 - Intended Environment For Use

4.1 Labeling reflects the statement: "Federal (USA) Law restricts this device to sale by or on the order of a physician."

4.2 May be used in hospital as well as the home.

5 - Legally Marketed Predicate Devices:

5.1 ACE® - Aerosol Cloud Enhancer, manufactured by DHD Healthcare, Canastota, New York.

5.2 Aerochamber®, manufactured by Monaghan Medical Corporation, Plattsburgh, New York.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number ____