K981167

JUN 18 1998

510(k) SUMMARY
As Required by 807.92(c)

3-4-98

1. **Submitter:** DHD Healthcare
125 Rasbach Street
Canastota, NY 13032

Phone: 315-697-2221
Fax: 315-697-8083

Contact: Jean Wallace, Manager, Regulatory Affairs

2. **Device Name**
- Trade Name - Stealth/Pilot (Final Name to Be Determined)
- Common name - MDI Spacer with Facemask
Classification name - Spacer - Class II - 868.5630
Oxygen Mask - Class 1 - 868.5580

3. **Predicate Device:**
1- "ACE" MDI Spacer
510(k)'s K913326A, K953206, K961973
DHD
Canastota, NY 13032

2- "Stealth" MDI Spacer
510(k) K973532
DHD
Canastota, NY 13032

4. **Device Description:** The Pilot device is a mask attachment for the Stealth Metered Dose Inhaler (MDI) Spacer. The Pilot mask fits directly onto the Stealth MDI Spacer.

Pilot is a single piece, injection molded, silicone rubber piece. It is intended for single patient use and may be disassembled from the Stealth MDI for convenient cleaning by washing the device, by hand, in warm soapy water.

The Pilot mask will be available in several sizes. and large masks. The mask sizes are designed to fit comfortably to a users face.

The masks also include a tapered fitting designed to mate with the Stealth mouthpiece. The tapered fitting includes a small ledge which serves as a stop, preventing the mask from being advanced too far onto the Stealth mouthpiece.

5. **Intended Use**
Pilot is a one piece, silicone rubber face mask that may be attached to the Stealth MDI holding chamber as an interface between the Stealth MDI and the patient's face/mouth region. 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).

6. **Technological Information**

6.1 The mask must fit securely to the Stealth MDI spacer and be easily removed for cleaning. The tapered interface between the Pilot mask and Stealth mouthpiece meets this requirement. No testing is required. **Pilot meets this requirement**.

6.2 The mask shall be available in three sizes. As shown by the drawings in the device description, the Pilot mask will be available in small, medium and large sizes. No testing is required. **Pilot meets this requirement.**

6.3 The mask must not interfere with MDI spacer performance. The mask system does not contain any valving, nor does the mask interface interfere with any of the functional areas of the Stealth spacer. No additional testing is required. **Pilot meets this requirement**.

6.4 The mask shall be manufactured from a clear or translucent elastomer. The Bayer LSR 20 series of silicone rubber is clear/translucent. No additional testing is required. **Pilot meets this requirement.**

7. **Summary of Studies**
There were no specific studies completed in association with this submission.

8. **Conclusions Drawn from Studies**
None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1998

Mr. Jean Wallace
Manager, Regulatory Affairs
DHD Healthcare
One Madison Street
Wampsville, NY 13163

Re: K981167
Stealth Pilot Kit
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: March 23, 1998
Received: April 1, 1998

Dear Mr. 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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,

Wolf Sparrow MD for

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): **Addendum to K973532**

Device Name: Stealth Metered Dose Inhaler Kit - **Adding Pilot Face Mask**

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). **Pilot is a one piece, silicone rubber face mask that may be attached to the Stealth MDI holding chamber as an interface between the Stealth MDI and the patient's face/mouth region.**

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.

2.3 When used with the Stealth Spacer, the Pilot face mask reduces coordination and technique problems associated with MDI drug delivery in lieu of the Stealth Mouthpiece.

3 - Target Patient Population:

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

3.2 Patients requiring mask interface. Pilot allows a clinical choice for use of the Stealth MDI spacer with a mouthpiece and/or a mask .

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 Stealth Metered Dose Inhaler(MDI) Spacer, manufactured by DHD Healthcare, Canastota, NY 13032

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Wdy Sapunka MD

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981167

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)