510(k) Summary

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

   Phone: 315-697-2221
   Fax: 315-697-5191

   Contact: Lawrence Weinstein, Technology Manager

2. Device Name
   a. Trade name: Boeing (final name tbd)
   b. Common name: Positive Airway Pressure (PAP) Device
   c. Classification name: Incentive Spirometer - 868.5690

3. Predicate Device: TheraPEP®, K962749, K944900
   DHD Healthcare Corporation
   125 Rasbach Street
   Canastota, NY 13032

4. Device Description
   The DHD Boeing is a single-patient-use Respiratory Therapy device. The standard system consists of a flow amplification body, compressed oxygen/air tubing, pressure port cap, and mouthpiece. The mouthpiece can be replaced with a mask.

5. Intended Use
   Positive Airway Pressure (PAP) Therapy for the treatment and prevention of atelectasis.

6. Technological Characteristics Compared to Predicate
   The DHD Boeing utilizes standard institutional provided compressed air or oxygen in conjunction with patient breathing to provide positive airway pressure. TheraPEP utilizes a restrictive orifice in conjunction with patient breathing to provide positive airway pressure. Both Boeing and the predicate device allow adjustment to achieve the desired patient airway pressure for the same range of breathing rates.

7. Summary of Studies
   The non-clinical bench testing performed compares the DHD Boeing against the predicate device and against its own performance specifications. These areas which define the performance of the device include: airway pressure (expiratory and inspiratory) and supplemental oxygen delivery. In each test Boeing performed substantially equivalent to the predicate device and met its specifications.

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8. Conclusions Drawn from the Studies
   For the common indications for use, Boeing performs substantially equivalent to the predicate device. In the opinion of DHD Healthcare Corporation, it is substantially equivalent to the predicate device and does not adversely affect safety and effectiveness compared to the predicate device.

TheraPEP is a registered trademark of DHD Healthcare Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

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

Re: K991300
Boeing, Positive Airway Pressure (PAP) Therapy Device
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: April 9, 1999
Received: April 16, 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,

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

Intended Use Statement

510(k) Number (if known):_____

Device Name: Boeing

Indications For Use:

1. **Purpose/Claims:**
   Boeing is indicated for the treatment and prevention of atelectasis. Boeing facilitates opening of airways in patients requiring prevention or treatment of atelectasis. Boeing also has the ability to provide supplemental oxygen when used with compressed oxygen.
2. **Target Patient Population:**
   Patients requiring therapy for treatment and prevention of atelectasis who are capable of following directions for Positive Airway Pressure (PAP) therapy.
3. **Intended Environment For Use:**
   3.1. Labeling reflects the statement: "Federal (USA) Law restricts this device to sale by or on the order of a physician."
   3.2. Boeing is intended for use in a hospital.
4. **Legally Marketed Predicate Device:**

Name:	TheraPEP	
Manufacturer:	DHD Healthcare Corporation 125 Rasbach Street Canastota, NY 13032 Tel: 315-697-2221 FAX: 315-697-5191	510(k) No. K962749 & K944900

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

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Chal Chu for JXH

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991300