K983467

APR 2

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

9-23-98

1. **Submitter:**

DHD Healthcare
125 Rasbach Street
Canastota, NY 13032

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

Contact: Jean Wallace, Manager, Regulatory Affairs

2. **Device Name**
   - Trade Name - TheraPEP® Kits
   - Common name - Positive Expiratory Pressure (PEP) Kit with Nebulizer
   - Classification name - Incentive Spirometer - 868.5690

3. **Predicate Device:** RESISTEX® 510(K) k954492

4. **Device Description** The DHD TheraPEP® is a single-patient-use Respiratory Therapy device. The standard system consists of a resistor, pressure range indicator, pressure port adapter, and mouthpiece. The mask may be substituted for the mouthpiece. Pressure monitoring is optional, and the pressure port adapter is removable.

   Air and aerosolized drugs are drawn in through the inlet of TheraPEP, which is opposite the mouthpiece end of the device. The air and aerosolized drug passes by the inlet valve which baffles out some of the medication, primarily large diameter particles of aerosolized drug which can not be absorbed by the patient's lung tissue. The air and respirable diameter particles of the aerosolized drug continue undeterred past the inlet device and through the device past the mouthpiece and into the patient's body. As the user begins exhaling, the inlet valve closes, forcing all of the air from the lungs out the selected orifice in the selector dial.

   The MDI with spacer or Nebulizer may be connected directly or by means of an adapter to the 22mm O.D. inlet end (opposite mouthpiece end) of the TheraPEP device. Positive Expiratory Pressure (PEP) occurs during exhalation and aerosol drug delivery occurs during inspiration. Use of an MDI Spacer and/or Nebulizer requires the same technique of breathing for inhalation and breath hold as does PEP therapy. A patient would be instructed by a clinician to take in a larger than normal breath for PEP Therapy or Aerosol Drug delivery followed by a short breath hold prior to exhalation. PEP occurs during exhalation and helps prolong exhalation plus keeps airways open longer thereby helping to move secretions, increase the transpulmonary pressure gradient, and resolve atelectasis.

5. **Intended Use**
   The DHD TheraPEP® is intended for use as a Positive Expiratory Pressure Device for patients suffering from Cystic Fibrosis, lung diseases with secretory problems, and to prevent or reverse atelectasis. *The device may be used in conjuction with aerosol drug therapy.* (Note that added claims are indicated in italics).

6. **Technological Information**

No basic technological changes as this submission is to add a claim and nebulizer components that are currently available in the market place.

7. **Summary of Studies**

The purpose of Phase I was to complete particle size distribution data using cascade impaction measurement, for the effect of expiratory resistance on metered dose inhaler (MDI) and small volume nebulizer (SVN) delivery of aerosolized albuterol (Proventil® and Proventil HFA) by metered dose inhaler (MDI) and aerosolized albuterol (Proventil®) by SVN. These tests were conducted using various products currently on the market such as the 1) Ace® Aerosol Cloud Enhancer MDI Spacer, reference 510(k) K953206, and three brands of SVN's, Airlife Misty Neb, Salter Neb and the Vortran Uni-Heart using albuterol sulfate (Proventil®), solution for inhalation.

The purpose of Phase II evaluation testing was to complete particle size distribution data using cascade impaction measurement, for the effect of expiratory resistance on small volume nebulizer (SVN) delivery of aerosol medication. Specifically, the effect of two expiratory resistance devices (TheraPEP, Resistex) on nebulized drug delivery was investigated using metaproterenol (Alupent®) and cromolyn sodium (Intal ®). This represents follow-up measures to the previous project testing MDI and nebulizer delivery of albuterol (Proventil®) with expiratory resistance.

8. **Conclusions Drawn from Studies**

The conclusions drawn from this evaluation were that there is no difference in albuterol drug delivery for MDI with the Ace® spacer, with or without the TheraPEP® attached in place of the Ace® mouthpiece, for either the CFC or the HFA formulations of albuterol. The results reported also indicate that there is no difference in albuterol drug delivery with the Misty Neb, the Salter or the Uni-Heart nebulizers between the TheraPEP® and the Resistex®.

Additional conclusions drawn indicate that there is no difference statistically in either total drug mass delivered, or respirable drug mass delivered, with Intal® (cromolyn sodium) or with Alupent® (metaproterenol sulfate) between the TheraPEP® and the Resistex devices attached to any of the three brands of nebulizer (Misty Neb, Salter, Uni-Heart). In each individual trial, larger amounts of total and respirable drug mass, for both drugs, were recovered with the TheraPEP® compared to the Resistex® device. However, the greater drug delivery with the TheraPEP® did not achieve statistical significance with the small sample size (n=3) and with the conservative nonparametric Wilcoxon statistic.

The added claim (the device may be combined with aerosol drug delivery) for PEP therapy will not adversely affect the safety and effectiveness of the TheraPEP device when utilized for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

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

Re: K983467
TheraPEP®
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: January 15, 1999
Received: January 19, 1999

Dear Mr. Weinstein:

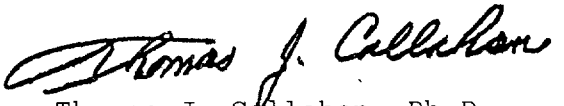
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Addendum - TheraPEP®510(k) Submission – K983467 **Section 2**
Intended Use Statement

Device Name: TheraPEP® (Positive Expiratory Pressure Therapy (PEP) Device)

1. Indications For Use:

The DHD TheraPEP is intended for use as a Positive Expiratory Pressure (PEP) device. It may also be used simultaneously with aerosol drug delivery using a nebulizer or Metered Dose Inhaler (MDI) with spacer.

Ath A. Ciarlone Li

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

510(k) Number _____

(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)