510(k) Summary

DEC - 5 2000

1. Submitter:
   DHD Healthcare Corporation
   One Madison Street
   Wampsville, New York 13163

2. Contact:
   Lawrence Weinstein, Director of Technology
   Phone: 315-363-2330 Fax: 315-363-9462

3. Device Name:

Product Code Name:	Roadrunner
Trade name:	acapella
Common Name:	Positive Expiratory Pressure (PEP) Device
Classification Name:	Incentive Spirometer – 868.5690

4. Predicate Devices:
   - TheraPEP: K944900, K962749, K983467
   - Roadrunner (acapella) K991561

5. Device Description:
   acapella is indicated for use as a single patient use, hand held secretion clearance and lung expansion device that creates vibrating positive expiratory pressure when a patient exhales through the device. ***acapella may be used simultaneously with aerosol drug delivery (new claim).***

6. Intended Use:
   Positive Expiratory Pressure (PEP) Therapy with acapella ***may be used simultaneously with aerosol drug delivery (new claim).***

7. Technological Characteristics Compared to Predicate:
   TheraPEP and acapella both provide PEP therapy and contain 22 mm OD connections at a one-way valve to allow for the delivery of aerosol medications.

8. Summary of Studies:
   Cascade impact testing was conducted comparing acapella to TheraPEP using three different nebulizers and two different drugs. Results show that acapella meets specifications and performs comparably to TheraPEP.

9. Conclusion Drawn from Studies
   acapella drug delivery is comparable to TheraPEP and meets specifications. The added claim that acapella may be combined with aerosol drug delivery during PEP therapy will not adversely affect the safety and effectiveness of acapella.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

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

Re: K002768
Acapella
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: September 1, 2000
Received: September 6, 2000

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K002768

Indications For Use/Purpose:

acapella is intended for use as a Positive Expiratory Pressure (PEP) device. ***It may also be used simultaneously with nebulized aerosol drug delivery.***

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002768

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

(Optional Format 1-2-96)