JAN 21 2000

K993629

ABI Vest™
By American Biosystems, Inc.
So everyone can breathe a little easier.™

26 October 1999

SUMMARY OF SAFETY AND EFFECTIVENESS
This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Submitter: Eric J. Larson
Manager of Quality Systems and Regulatory Affairs
American Biosystems, Inc.
20 Yorkton Court, St. Paul, MN 55117
Phone: (651) 234-1211 Fax: (651) 490-1484

Contact person: Eric J. Larson

Name of Device: ABI Vest™ Airway Clearance System

Classification: Powered Percussor, Class II

Predicate Device: ThAIRapy® Vest System, 510(K) number: **K965192**

Description of Device:
The ABI Vest Airway Clearance System is a high-frequency chest wall oscillator designed to be used in a wide variety of settings for enhancing the mobilization of bronchial secretions. The primary components of the ABI Vest Airway Clearance System include an air-pulse generator and an inflatable vest. Oscillating positive pressure air pulses are applied to the vest by the air-pulse generator. The resulting pressure pulses cause the vest to inflate and deflate against the chest of the patient creating high-frequency chest wall oscillation and mobilization of bronchial secretions. The frequency of the air pulse is operator controlled and adjustable from 5 to 25 Hz.

American Biosystems, Inc.
20 Yorkton Court
St. Paul, Minnesota 55117-1065

Tel: (651) 490-1468
(800) 426-4224
Fax: (651) 490-1484

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:
The intended use of the ABI Vest Airway Clearance System is to promote airway clearance or improve bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. The indications typically follow the Clinical Practice Guideline published by the American Association for Respiratory Care (AARC) 1991. In addition, the device is also indicated for the purpose of collecting mucus for diagnostic evaluation.

Comparison of Technological Characteristics:
The ABI Vest System is identical to the previously cleared ABI Vest™ Airway Clearance System (a.k.a. ThAIRapy® Vest System) (K965192), which is intended to promote airway clearance or improve bronchial drainage by enhancing the mobilization of bronchial secretions when external manipulation of the thorax is the physician's choice of treatment. The only reason for this submission is to include in the device's indication for use that the device can be used for the mobilization of bronchial secretions to promote bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

Performance Testing:
None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2000

Mr. Eric J. Larson
American Biosystems, Inc.
20 Yorkton Court
St. Paul, MN 55117

Re: K993629
ABI Vest™ Airway Clearance System
Regulatory Class: II (two)
Product Code: 73 BYI
Dated: October 26, 1999
Received: October 27, 1999

Dear Mr. Larson:

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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known) K993629

Device Name: ABIVest™ Airway Clearance System

Indications for use:

The intended use of the ABIVest™ Airway Clearance System is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy[1] (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the ABIVest™ Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

1. Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC clinical practice guideline: postural drainage therapy. Respiratory Care 1991; 36: 1418 – 1426.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993629

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)