K965192

AmericanBiosystems
ThAIRapy•Vest

01 Dec. 96 JUN 24 1997

## SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Submitter:
American Biosystems, Inc., 1375 Wolters Blvd., Suite 116, St. Paul MN 55110
(612)490-1468
Contact: Phillip R. Rose, Quality Assurance and Regulatory Affairs

Name of Device:
ThAIRapy® System
Classification: Powered Percussor, Class II

Predicate Device:
ThAIRapy® System, K884098

Description of Device:
The ThAIRapy® System is a high-frequency chest wall oscillator designed be used in a wide variety of settings for enhancing the mobilization of bronchial secretions. The primary components of the ThAIRapy® System include an air oscillator and an inflatable vest. Oscillating positive pressure air pulses are applied to the vest by the air oscillator. 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. Frequency of the pulse air is operator controlled and adjustable from 5 to 25 Hz.

Intended Use:
The intended use of the ThAIRapy® 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.

Comparison of Technological Characteristics:
The modified ThAIRapy® System has been thoroughly tested to determine the impact of the changes on safety and effectiveness. All modifications have been evaluated according to categories of Electrical, Chemical, Output, Operation, and Infection Control. In all categories, the modified device remained substantially equivalent to the predicate ThAIRapy® System. The major difference to the original predicate ThAIRapy® System is the change of the change of the air blower component to a blower from another supplier and changing generation of the air pulse oscillations from a rotary valve to utilization of reciprocating bellows. Usage of an inflatable vest with two connecting hoses continues as the same method as the original predicate for providing the external manipulation of the thorax.

Performance Testing:
Pressures obtained in the inflatable vests for the ThAIRapy® System were recorded and compared with pressures for the predicate. Results depict pressures that are consistent with the predicate.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Phillip R. Rose
American Biosystems, Inc.
1375 Wolters Boulevard, Suite 116
St. Paul, Minnesota 55110

Re: K965192
ThAIRapy® System
Regulatory Class: II (two)
Product Code: 73 BYI
Dated: April 4, 1997
Received: April 7, 1997

Dear Mr. Rose:

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 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/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

510(K) Number (if known) K965192

Device Name ThAIRapy® Vest System

Indications for use:

The intended use of the modified ThAIRapy® Vest is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of 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 Practice Guidelines for Postural Drainage Therapy.[1] According to AARC guidelines, the goals of airway clearance therapy are to improve mobilization of bronchial secretions, match ventilation and perfusion, and normalize functional residual capacity. Specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with secretion clearance, or presence of atelectasis caused by mucus plugging.

[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)

Richard N. Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K965192

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