K061495

JUL 18 2007

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR §807.92.

Submission Date: February 2, 2007

Submitter Information:

Company Name: Deep Breeze Ltd.

Company Address: 2 Hailan Street, North Industrial Park
P.O. Box 140, Or-Akiva, 30600, Israel

Company Contact: Alon Kushnir
Vice President, Regulatory and Medical Affairs
Tel: 9-724-626-6650
Fax: 9-724-626-6649
alonk@deepbreeze.com

Official Correspondent: Philip J. Phillips
Director, Medical Device Practice
Becker & Associates Consulting, Inc.
Tel: 202-822-1850
Fax: 202-822-1859

US Agent: Becker & Associates Consulting, Inc.
2001 Pennsylvania Avenue, NW, Suite 950
Washington, DC 20006
Tel: 202-822-1850
Fax: 202-822-1859

Device Information:

Trade Name:	VR Lung Electrosonograph
Common Name:	Electronic stethoscope
Classification Name:	Electronic Stethoscope, 870.1875 Diagnostic pulmonary-function interpretation calculator, 868.1900
Device Class:	Class II

Predicate Device: Meditron Stethoscope System, Meditron AS (k991367)
STG Monitor Multichannel Lung Sound Analysis System (k012387)

Device Description: The VR Lung Electrosonograph is intended for use in monitoring and recording lung sounds. The VR Lung Electrosonograph is a non-invasive device consisting of three primary components: 1) Electronic stethoscopes designed to collect lung sounds via dermal contact with the human thorax; 2) a Digital Collection Module ("DCM") for the conversion of analog data to digital data; and 3) a mobile computer workstation to assist in processing, displaying, and/or storing recorded information. The VR Lung Electrosonograph is intended to be used by trained healthcare practitioners, and has been designed to accommodate most clinic, treatment center, or hospital settings. While the VR Lung Electrosonograph may aid in diagnosis, the device is not intended to be used as a diagnostic instrument.

Intended Use: The VR Lung Electrosonograph is intended for use in monitoring and recording lung sounds.

Comparison to Predicate Device:

Deep Breeze's VR Lung Electrosonograph is substantially equivalent to the Meditron Stethoscope System, manufactured by Meditron AS. Furthermore, the VR Lung Electrosonograph is similar in its technological characteristics to the STG Monitor Multichannel Lung Sound Analyzer by Stethographics, Inc. The VR Lung Electrosonograph is a non-invasive device that has the same basic

intended use and technological characteristics (i.e., design, materials, energy source) as the cited predicates.

Conclusion:

The VR Lung Electrosonograph falls within the same generic types of devices as defined by 21 CFR §870.1875 and 21 CFR § 868.1900. That is, the VR Lung Electrosonograph and the predicates do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness. The VR Lung Electrosonograph is also similar in technology, in the use of a visual display of sounds, as the STG Monitor Multichannel Lung Sound Analysis System. Furthermore, the regulatory controls applicable to the predicate devices are sufficient to provide reasonable assurance of the safety and effectiveness of the VR Lung Electrosonograph.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

Deep Breeze, Limited
C/O Mr. Phillip J. Phillips
Director, Medical Device Practice
Becker & Associates Consulting, Incorporated
2001 Pennsylvania Avenue NW, Suite 950
Washington, DC 20006

Re: K061495
Trade/Device Name: VR Lung Electrosonograph
Regulation Number: 870.1875
Regulation Name: Stethoscope
Regulatory Class: II
Product Code: OCR
Dated: May 10, 2007
Received: May 10, 2007

Dear Mr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K061495

Device Name: VR Lung Electrosonograph

Indications for Use:

The VR Lung Electrosonograph is intended for use in monitoring and recording lung sounds.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K061495