K073582

510(k) Summary

Deep Breeze, Ltd

VRI_{XV} System

OCT 15 2008

Applicant's Name:

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US Correspondent:

Becker & Associates Consulting, Inc.
Attn: Jeffrey A. Baetz
2001 Pennsylvania Ave. NW, #950
Washington, DC 20006

Date Prepared:

December 20, 2007

Trade Name:

VRI_{XV} System

Classification Name:

Electronic Stethoscope (21 CFR 870.1875)

Classification:

Class II; Product Code OCR

Predicate Devices:

The VRI_{XV} System is substantially equivalent to the previous version of the device, the VR Lung Electrosonograph (K061495).

Device Description:

The modified VR Lung Electrosonograph, the VRI_{XV} is intended for use in monitoring and recording lung sounds. The VRI_{XV} is a non-invasive device designed to facilitate visualization and monitoring of regionally distributed vibration energy. The VRI_{XV} is comprised 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 VRI_{XV} represents a natural progression in the company's desire to improve bedside monitoring capabilities, and is designed to provide lung imaging capability in spontaneously breathing patients, as well as mechanically ventilated patients. In the latter, monitoring capabilities are enhanced by the synchronization of the VRI_{XV} image and vibration energy graph, with the pressure and flow waveform sampled from a ventilator. All dynamic images can be viewed as video file or frame-by-frame. The vibration energy of the lungs can be depicted in grayscale or color. Patient recording and all associated data are stored in the VRI_{XV} system. Current and/or previous recordings can be viewed side-by-side in order to compare patients' lung sound images during hospitalization. These recordings and associated reports can be viewed or exported for offline viewing or printed on a conventional PC computer.

The VRI_{XV} is intended to be used by trained healthcare practitioners and has been designed to accommodate most clinic, treatment center, or hospital settings. The VRI_{XV} is not intended to be used as a diagnostic instrument.

Intended Use:

The VRI_{XV} is intended for use in monitoring and recording lung sounds.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the VRI_{XV} System complies with the voluntary standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, AAMI / ISO 14971-1 and AAMI ANSI ISO 10993-1:2003.

Performance Data & Substantial Equivalence

The VRI_{XV} System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the VR Lung Electrosonograph cleared under K061495.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Deep Breeze Limited
C/O Mr. Jeffrey A. Baetz
Project Manager
Becker & Associates Consulting, Incorporated
2001 Pennsylvania Avenue, N.W. #950
Washington, DC 20006

Re: K073582
Trade/Device Name: VRI_{XV} System
Regulation Number: 21 CFR 870.1875(b)
Regulation Name: Electronic Stethoscope
Regulatory Class: II
Product Code: OCR
Dated: September 16, 2008
Received: September 16, 2008

Dear Mr. Baetz:

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 Register.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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 STATEMENT

510(k) Number (if known):_____

Device Name: VRI$_{XV}$ System

Indications for Use:

The VRI$_{XV}$ is intended for use in monitoring and recording lung sounds.

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

510(k) Number: K073582

Prescription Use __√__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (Part 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)