

510(K) SUMMARY

Submission Date: June 11, 2009

Preparation Date: February 26, 2010

MAR - 4 2010

Submitter Information:

Company Name: Deep Breeze Ltd.

Applicant Address: Deep Breeze, Ltd.
Attn: Alon Kushnir
2 Hailan Street, North Industrial Park
PO Box 140, Or-Akiva, 30600, Israel
Telephone: +972 (4) 626-6650
Fax: +972 (4) 626-6649

Contact Person: Jack A. Kent
Project Manager, Strategic Consulting
Becker & Associates Consulting, Inc.
2001 Pennsylvania Avenue NW, Suite 950
Washington, DC 20006
Telephone: (202) 822-1850
Fax: (202) 822-1859
Email: jack.kent@becker-consult.com

Device Information:

Trade Name: VRI_{XP}

Common Name: Electronic Stethoscope

Classification Name: Electronic Stethoscope

Device Class: Class II, 21 CFR 870.1875(b)
Product Code OCR

Predicate Devices: VRI_{XV} (K073582)
Deep Breeze, Ltd.
Class II

VR Lung Electrosonograph (K06 I495)
Deep Breeze, Ltd.
Class II

Meditron Stethoscope System (K991367)
Meditron AS
Class II

STG Monitor Multichannel Lung Sound Analysis
System (K012387)
Stethographics, Inc.
Class II

Device Description:

The VRI_{XP} is a non-invasive, non-energy emitting device indicated for monitoring and recording lung sounds and automatic detection of crackles and wheezes. When interpreted by physicians with general medical training and experience, the VRI_{XP} aids in diagnosis, monitoring, and patient management.

The VRI_{XP} consists of same fundamental components as its predecessors the VRLE and the VRI_{XV}, which are 1) sound sensors designed to collect lung sounds via dermal contact with human skin; 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 recording information.

During the breathing process, the VRI_{XP} detects lung sounds (i.e., acoustic energy) and converts them into a visual display, which can be viewed via a personal computer (PC) monitor and stored for future review. The device is designed to record breath sounds based on sensor location. Additionally, the VRI_{XP} has an automated feature for detecting sounds consistent with crackles and wheezes for further clinical evaluation. Lung sounds can be viewed collectively as a grayscale image, as well as audibly by sensor. This latter feature provides greater flexibility for physicians to validate visual lung data by applying his or her previous clinical experience with conventional auscultation (gold standard).

Indications for Use:

The VRI_{XP} is intended for monitoring and recording lung sounds and automatic detection of crackles and wheezes. When interpreted by physicians with general medical training and experience, the VRI_{XP} aids in diagnosis and patient management. The VRI_{XP} is intended to be used in healthcare facilities on adults, adolescents, and/or children over the height of 2 feet 9 inches.

Comparison to Predicate Device:

The VRI_{XP} is substantially equivalent to the VRLE (manufactured by Deep Breeze; K061495), the VRI_{XV} (manufactured by Deep Breeze; K073582), and the Meditron stethoscope system (manufactured by Meditron AS; K991367). The VRI_{XP} and these three predicate devices share the same intended use and fundamental technological

characteristics; the VRLE and VRI_{XV} are indicated for monitoring and recording lung sounds, while the Meditron stethoscope system is indicated for use as an aid in diagnosis, treatment, and monitoring.

Additionally, the VRI_{XP} has the same fundamental technological characteristics as the VRLE, VRI_{XV}, and Meditron stethoscope system. Like the VRI_{XP}, the VRLE and VRI_{XV} use sound sensors to collect lung sounds via dermal contact, which is then converted to a visual display. The Meditron stethoscope system amplifies sound from the body's internal organs without introducing signals or energy into the body, and in fact, represents the electronic sensors contained within the VRLE and VRI_{XP}. Additionally, the Meditron stethoscope system contains a software application that is designed to provide computer-aided recordings with the electronic stethoscope and to store these recordings along with other appropriate patient information, same as the VRI_{XP}.

The STG Monitor Multichannel Lung Sounds Analysis System (STG) is a predicate device for the clearance of the VRI_{XP}. It has the same intended use, namely: "automatic detection of crackles and wheezes." The VRI_{XP} testing has demonstrated similar accuracy in crackles and wheezes detection as the reported accuracy of the predicate device.

Non-clinical testing has been conducted to demonstrate the performance of VRI_{XP} and that it meets its intended use. The VRI_{XP} has been evaluated for biocompatibility, and appropriate software verification and validation testing was conducted. Pre-determined product specifications were met.

Conclusion:

The VRI_{XP} falls within the generic type of device as defined by 21 CFR 870.1875(b), Electronic Stethoscope. The VRI_{XP} does not differ from the intended use or fundamental technological characteristics of the cited predicates, the VRLE, VRI_{XV}, or the Meditron stethoscope system, and therefore is substantially equivalent to them.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Deep Breeze, Limited
C/O Mr. Jack Kent
Project Manager, Strategic Consulting
Becker & Associates Consulting, Incorporated
2001 Pennsylvania Avenue Northwest, Suite 950
Washington, DC 20006

MAR - 4 2010

Re: K091732
Trade Name: VRI_{XP}
Regulation Number: 21 CFR 870.1875(b)
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: OCR
Dated: March 4, 2010
Received: March 4, 2010

Dear Mr. Kent:

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 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.

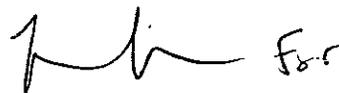
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K091732

Device Name: VRI_{XP}

Indications for Use:

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

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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