510(k) Summary

Vasomedical, Incorporated

Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder 2301 and Ambulatory ECG and Blood Pressure Recorder Analysis Software

APR - 2 2010

1. **Date Prepared:** 22 March, 2010

2. **Submitter's Name and Address:**
   Vasomedical, Inc.
   180 Linden Ave.
   Westbury, NY 11590

3. **Contact Person:**
   Richard Gordon
   Director, Regulatory and Quality Affairs
   Vasomedical, Incorporated
   Telephone: (516) 997-4600
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   E-mail: rgordon@vasomedical.com

4. **Device Name:** Combined Ambulatory ECG and Blood Pressure Recorder
   Proprietary Names: Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder 2301 and Analysis Software
   Common Name: Combined Ambulatory ECG and Blood Pressure Recorder 2301
   Classification Name: 870.2800 Medical Magnetic Tape Recorder
   870.1130 Non invasive Blood Pressure Measurement System

5. **Predicate Device:** The AECG/BP Recorder listed above is substantially equivalent to the SunTech Medical Instruments Inc., Automatic Blood Pressure Measurement System, Oscar 2 and the Vasomedical-Biox 1305, 3 Channel ECG Holter Monitor and CB Series Analysis Software. FDA granted 510(k) clearances for these predicate devices on October 25, 2000 (K003004), and April 1, 2009 (K083820).

6. **Device Description:** Vasomedical's Ambulatory ECG and Blood Pressure Recorder is intended to be used as a combined Holter Ambulatory Electrocardiograph device and a non-invasive Ambulatory Blood Pressure Monitor for the purpose of screening ECG rhythms and blood pressure measurements for periods up to 24 hours. Blood Pressure measurements are obtained using oscillometric signals at intervals set by the physician or on demand. Cardiac rhythm is acquired by 3 channel ECG signals. The Recorders are intended for adults and children over the age of six years old.

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The CB series AECG/BP Analysis system is a PC based diagnostic application running on a Microsoft Windows operating system. It is designed in conjunction with the CB series Holter Recorder and analyzes prerecorded patient's ECG and/or ABP data that has been stored by CB series Recorder, or other compatible Holter Recorders. The system provides multi-channel full disclosure for arrhythmia and ST events and synchronous three channel ECG and ABP pulses, and creates summary tables, statistics, trends, and final report regarding a variety of cardiac data indices. The cardiac data provided by the system is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

The Recorders are portable, microprocessor based devices that are worn by a patient with the use of a carrying case and strap.

Model 2301 specifications are listed in **Table 1** below:

Lead	**3**		**Dimensions**	**4.88x2.68x1.22"**	
Electrode	**5 or 7**		**Weight**	**6.35 oz. w/o batteries**	
Lead wire type	**Lead-7C/5C**		**Storage**	**SD Memory Card**	
Display	**LCD**		**Memory**	**512 MB or4 more**	
Batteries	**4 "AA" alkaline**		**Sample Rate**	**256 Hz/Channel 2048Hz Pacemaker Detection**	
BP Cuff	**Medium**		**Resolution**	**10 Bits**	
Carrying Case/ Strap	**Supplied**		**Infrared Adaptor**	**Supplied**	
Card Reader	**Supplied**				

Table 1: Model CB2301 Specifications

7. **Intended Use:**

Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder, #2301, is a Non-Invasive device intended to acquire Ambulatory 3 Channel ECG signals and non- invasive Oscillometric Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG Signals. The Recorders are intended for adults and children who are over the age of six years.

Vasomedical-Biox Ambulatory ECG CB Series Analysis System Software allows transfer of ECG and Blood Pressure data from the Recorder to a Windows based PC program via a removable and

large capacity storage card (SD) for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostic evaluations of this data.

The system is only for measurement, recording and display. It makes no diagnosis.

Refer to Attachment I, Vasomedical-Biox Model 2301 AECGBP Operator's Manual, Sections 2.2, Indications for Use, 2.2.1 Intended Use and 2.2.2 for Contraindications.

8. Comparison of Technological Characteristics: Technological and functional characteristics of the device listed in this 510(k) Premarket Notification is essentially the same as those of the predicate devices. The device listed in this 510(k) Premarket Notification is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 2 2010

Vasomedical, Inc.
c/o Mr. Richard Gordon
Manager, Regulatory and Quality Affairs
180 Linden Ave
Westbury, NY 11590

Re: K092785
Vasomedical-Biox 2301 Combined Ambulatory ECG and Blood Pressure Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH and DXN
Dated: March 22, 2010
Received: March 24, 2010

Dear Mr. Gordon:

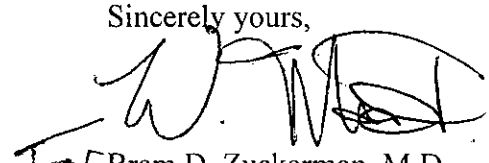
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: k092785

Device Name: Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder 2301 and Analysis Software

Indications for Use: Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder is a Non-Invasive oscillometric device intended to acquire Ambulatory 3 Channel ECG signals and non- invasive Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. The Recorders are intended for adults and children Who are over the age of six years.

Vasomedical-Biox Ambulatory ECG CB Series Analysis System Software allows transfer of ECG and Blood Pressure data from the Recorder to a Windows based PC-based computer program via a removable and large capacity storage card (SD) for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostic evaluations of this data.

The system is only for measurement, recording and display. It makes no diagnosis.

Prescription Use: YES AND/OR **Over-The-Counter Use:** NO
(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 Cardiovascular Devices

510(k) Number_____