DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 1, 2014

Bomed Inc
B. Bo Sramek
59-440 Pili Pl.
Kamuela, HI 96743 US

Re: K132892
Trade/Device Name: Tebco-W
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, preprogrammed diagnostic computer
Regulatory Class: Class II
Product Code: DXG
Dated: June 17, 2014
Received: June 30, 2014

Dear B. Bo Sramek:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ken Skodacek 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:

Device Name: TEBCO-W

Indications For Use: Adults, Hospital, Cardiology, Internal medicine

TEBCO-W is indicated for noninvasive, continuous assessment and monitoring of the left-ventricular performance and global blood flow (Stroke Index, SI and Cardiac Index, CI) in adults, where use of invasive catheters is contraindicated.
The device may be used only on the order of a physician and is ”By prescription only.”
The intended use is physician’s office and cardiovascular physiology laboratory.

Prescription Use: Yes AND/OR Over-The-Counter Use: N/A

Ken Skodacek for

Bram Zuckerman

510(k) Summary of Substantial Equivalence
BoMed Inc.
TEBCO-W: K132892

21 CFR 807.92(a):

21 CFR 807.92(a) (1):

Submitter's name and address:

BoMed Inc.
59-440 Pili Pl.
Kamuela, HI 96743

Submitter's telephone number:

808-885-8463

Contact person:

B. Bo Sramek, Ph.D.
President
BoMed Inc.
59-440 Pili Pl.
Kamuela, HI 96743

Date this 510(k) Summary was prepared:

October 17, 2013

21 CFR 807.92(a) (2):

Trade Name of Device:	TEBCO-W; assigned 510(k)#: K132892
Common Name of the Device:	Bioimpedance Cardiac Output, Impedance Cardiograph, Impedance Plethysmograph
Regulatory Section:	21 CFR 870.2770 "Impedance Plethysmograph", and 21 CFR 870.1435 "Single-function, preprogrammed diagnostic computer"
Classification:	Class II
Product Code:	74 DXG

21 CFR 807.92(a) (3): **Legally marketed predicate device to which substantial equivalency is claimed**

The Predicate Device: TEBCO

Manufacturer: HEMO SAPINES INC.

Predicate Device K#: K962128

21 CFR 807.92(a) (4): **Description of the Device that is the subject of this premarket notification:**

TEBCO-W is the substantially equivalent **wireless** version of the existing **tethered** predicate device TEBCO (Thoracic Electrical Bioimpedance Cardiac Output, K962128). Both the TEBCO and TEBCO-W are a hardware component of a system for noninvasive measurement of Cardiac Output and other cardiodynamic parameters. The system comprises of TEBCO (or TEBCO-W) and a PC, which acts as a host system. TEBCO (or TEBCO-W) acquire the TEB and data via a patient cable attached to 8 electrodes placed on a patient's thorax. 4 out of 8 electrodes are also used to detect a patient's ECG signal, which is utilized by both devices as a system clock. They sample the instantaneous TEB values @ 5 msec sample rate, and send continuously the binary values of digital samples in packets every 20 msec via a serial communication link to a host system (a PC), where the TEB signals are reconstructed and displayed. Both TEBCO and TEBCO-W also measure the magnitude and timing of the TEB signal in reference to Q-time of the QRS complex, from which the Heart Rate and Stroke Index are calculated, calculate then the value of Cardiac Output and sent the digital values of these parameters via the same serial link once every heartbeat to the host system, where they are displayed.

This table lists the differences between TEBCO and TEBCO-W:

	TEBCO	**TEBCO-W**
TEB Measurement Current	7 µA RMS	7 µA RMS
Communication w/ host system	Tethered: Serial RS232 cable 4 or 6 bytes packets	Wireless: Serial – WiFi 4 or 6 bytes packets WiFi Band: 2.412 - 2.462 GHz Modulation: 802.11b Power: max 15 dBm ± 1.5 dB Security: WPA2

Connection to patient	8 thoracic electrodes, 8 patient leads, patient cable	8 thoracic electrodes, 8 patient leads, patient cable
Power	External AC-to-DC 5V power source	Built-in, externally re-chargeable four C-cells batteries
PC board size	One PCB 9.1” x 5.5”	Two piggy-back PCBs 4.5” x 2.5”
Patient mobility	Radius of patient movement limited by the length of patient cable (3 m)	Limited by the capability of the WiFi connection

21 CFR 807.92(a) (5): Intended use and labeled indications for use

The TEBCO-W (as was TEBCO) device is indicated for noninvasive monitoring and assessment of cardiovascular performance, where use of invasive catheters is contraindicated or expensive. TEBCO-W is labeled “For Professional Use Only” and can be used only on the order of a physician.

21 CFR 807.92(a) (6): Technological characteristics

The design, product technology, algorithms used in software, communication protocol, connection to the patient and use of the host system of TEBCO-W to display data are identical to the predicate device TEBCO. The differences are (a) the power source, where the external AC-to-DC converter used with TEBCO is replaced in TEBCO-W by 4 C-cells batteries recharged only externally, and (b) the tethered communication in TEBCO is replaced in TEBCO-W with a wireless communication, utilizing a built-in WiFi feature of today’s PC. TEBCO-W will represent a technological improvement to the predicate device TEBCO in two respects: The departure from AC power source improves a patient’s safety, while the wireless communication improves his mobility.

21 CFR 807.92(b):

21 CFR 807.92(b) (1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

The nonclinical test was performed in our laboratory:
During the Bench Test, a person representing a patient was being monitored by TEBCO-W carried on subject’s chest and his data were continually transmitted to the host system (Acer Aspire

V5-571P-6400 notebook) while the other equipment, representing potential WiFi interference source/recipient, was operating under its normal conditions:

We constructed a private WiFi secured network consisting of three different computers (iMac, Gateway M520X-CTC notebook and MacBook Air) and created a simple program in which all computers continuously communicated via their WiFi with each other. All utilized network computers have a manufacturer built-in WiFi circuit.
The monitored subject than moved around the lab and operator of each of the network computers and the operator of the TEBCO-W host system looked for presence of any disruption in service. We concentrated on TEBCO-W host system: The four digitized analog signals and the digital values of measured parameters are sent out by TEBCO-W every 20 msec in packets (see Attachment 007), while the digitized analog signal content of each packet represents a next dot on the displayed analog signal. Any transmission interference producing missing or erroneous packets would thus be clearly visible as a signal waveform inconsistency.
When no interference in this mode could be detected, the monitored subject than placed TEBCO-W adjacent to each of the network computers, also with no interference observable.

21 CFR 807.92(b) (2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

The Clinical Test took place at the North Hawaii Community Hospital, in its Intensive Care Unit. The subject/patient's monitoring was similar to the laboratory Bench Testing: During the Clinical Test, a person representing a patient was being monitored by TEBCO-W carried on subject's chest and his data were continually transmitted via its WiFi link to the host system (Acer Aspire V5-571P-6400 notebook) while all other ICU equipment (patient monitors and ventilators), representing potential interference source, was operating under its normal conditions:

Our subject, monitored by TEBCO-W, walked around the ICU without any observable interference either on the ICU patient monitor (that would indicate TEBCO-W as a source of interference) or on the TEBCO-W host system (which would indicate a TEBCO-W susceptibility to noise emitted by the ICU equipment).

Conclusion 1: TEBCO-W did not produce any interference with the ICU monitors and thus its function could not cause any life-threatening condition to the ICU patient.

Conclusion 2: The ICU setting – the most interference-rich environment – did not produce any observable interference with the TEBCO-W operation.

21 CFR 807.92(b) (3): Conclusions drawn from nonclinical and clinical tests

Based on the results of both nonclinical and clinical studies described in this 510(k) Submission above, we can conclude that TEBCO-W is as safe and effective (therefore substantially equivalent) as the predicate device TEBCO

…. End of 510(k) Summary….