K122281
p1/3

510(k) Summary of Safety and Effectiveness

Date: 7/19/12

AUG 29 2012

Submitter: BioMedix, Inc
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Device Name/Trade Name: PADnet 2.0
Common Name: Plethysmograph
Classification Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Classification: Listed as Class II
Panel Code: JOM
Regulation Number: 870.2780

Identification of Legally Marketed (Unmodified) Device (Predicate Device):

Name of Predicate	Manufacturer	Use	510(k)	Date Cleared
PADnet+	BioMedix	Plethysmograph	K073146	11/21/2007

Device Description:
The primary goal of the PADnet 2.0 system is to assess the blood vascular system and assist on the diagnosis of arterial and venous vascular disease. The currently released PADnet+ system already provides this type of functionality. With focus on the venous system, PADnet+ permits the assessment of venous reflux in the venous valvular system of the lower extremity. Its native functionality also permits the assessment of venous obstruction in the deep venous system. It accomplishes these ends using photo-plethysmography. Photo-plethysmography refers to a technique whereby localized volume changes due to an optically scattering/absorbant substance (e.g. blood) are measured. PADnet 2.0 adds the air plethysmography modality to the pre-existing venous test suite. Thus, only the methodology used for testing has been augmented. Indications for use are unchanged. With focus on the arterial system, PADnet+ permits the assessment of arterial insufficiency. It accomplishes this end using pneumo-plethysmography (air plethysmography). Pneumo-plethysmography refers to a technique whereby localized volume changes as measured by pressure changes in an inflated blood pressure cuff are recorded. This signal is assessed for waveform morphology and amplitude. Additional information regarding arterial insufficiency may be obtained by measurement of peak arterial systolic blood pressure. PADnet 2.0 uses oscillometry to assess limb blood pressure.

Indications for Use:
The BioMedix PADnet 2.0 is a non-invasive device used to assess the lower and upper extremity arterial and venous circulatory systems in order to assist in the identification of vascular disease. To assess the arterial system, PADnet 2.0 uses pulse volume recording, arterial pulse contour analysis, and segmental systolic & diastolic blood pressure measurements. To assess the venous valvular system, PADnet 2.0 measures venous refilling time. For identification of venous obstruction in the deep venous (below knee) system, PADnet 2.0 measures venous outflow rate. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non-intact skin.

Technological Comparison to (Unmodified) Predicate Device:
The following summary table of comparisons compares the PADNet 2.0 Device to the Previously Cleared PADNet+ Device.

#	Attribute	Modified Device PADnet 2.0	Previously Cleared Device: PADnet+	Same	Different
Indications for Use					
1	Patient Population	Male/Female Adult	Male/Female Adult	X	
2	Environment	Hospital or Clinic	Hospital or Clinic	X	
3	OTC or Prescription	Prescription	Prescrption	X	
Testing					
4	Pulse Volume Recording	Pneumo-Plethysmograph (Air Plethysmograph)	Pneumo-Plethysmograph (Air Plethysmograph)	X	
5	Segmental Pressure Measurement System	Oscillometric	Oscillometric	X	
6	Venous Tests	Pneumo-Plethysmograph & Photo-Plethysmography	Photo-Plethysmography		X
Contraindications					
7	Contraindications	No contraindications	No contraindications	X	
Sterility/Expiration Dating					
8	Supplied Non-sterile	Yes	Yes	X	
Energy Supplied					
9	Power Source	AC to DC Conversion	AC to DC Conversion	X	
Environmental Specifications					
10	Operating Temperature	0°C to +40°C	0°C to +40°C	X	
11	Operating Relative Humidity	15-90% RH	15-90% RH	X	
12	Storage Temperature	-40°C to +50°C	-40°C to +50°C	X	
13	Storage Humidity	5-95%RH	5-95%RH	X	
Physical					

14	Weight	5 lbs.	4 lbs.		X
15	Size	12 1/2"W X 10" D X 3 " H	12 1/2"W X 10" D X 3 " H	X	
Software/Firmware					
16	Data acquisition	Single Site	Single Site	X	
17	Software Controls	Operator Initiated	Operator Initiated	X	
Standards					
18	Electrical Safety	IEC/EN 60601-1-1	IEC/EN 60601-1-1	X	
19	EMC Compliance	IEC/EN 60601-2-2	IEC/EN 60601-2-2	X	
Cuffs					
20	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	
21	Cuff Bladder Deflation Method	Automatic Loop	Automatic Loop	X	
22	Inflation Method	Automatic	Automatic	X	
23	Cuff Sizes	Multiple	Multiple	X	
Reports					
24	Clinical Reports	Yes	Yes	X	
25	Printed Reports	Yes	Yes	X	

Summary of Performance Testing:
The PADnet 2.0 has been tested to meet the requirements of the applicable product and software requirements specifications. The PADnet 2.0 has also been tested or found otherwise to comply with applicable sections of the following standards:

- **Safety** - IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- **Electromagnetic Compatibility (EMC)** - EN/IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).

Conclusions:
The results of the tests discussed above, indicate that the modified BioMedix PADnet 2.0 device is as safe, as effective, and performs as well as or better than the non-modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 29 2012

BioMedix, Inc.
c/o Mr. Greg Hocking
Regulatory Affairs Manager
178 East Ninth Street
St. Paul, MN 55101

Re: K122281
Trade/Device Name: PADnet 2.0
Regulatory Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: II (two)
Product Code: 74 JOM
Dated: July 19, 2012
Received: July 30, 2012

Dear Mr. Hocking:

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

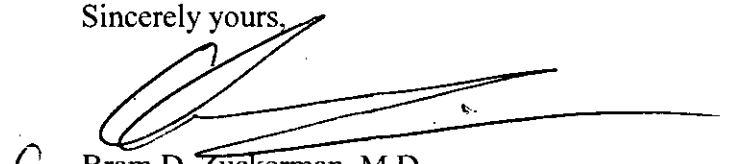
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 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/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,



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

Enclosure

K122281

Indications for Use

510(k) Number (if known): *To be determined*

Device Name: PADnet 2.0

Indications for Use:

The BioMedix PADnet 2.0 is a non-invasive device used to assess the lower and upper extremity arterial and venous circulatory systems in order to assist in the identification of vascular disease. To assess the arterial system, PADnet 2.0 uses pulse volume recording, arterial pulse contour analysis, and segmental systolic & diastolic blood pressure measurements. To assess the venous valvular system, PADnet 2.0 measures venous refilling time. For identification of venous obstruction in the deep venous (below knee) system, PADnet 2.0 measures venous outflow rate. It is intended to be used by healthcare professionals in a hospital or clinic environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non-intact skin.

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 Cardiovascular Devices

510(k) Number K122281