K042616
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OCT 1 2 2004

510(K) Summary of Safety and Effectiveness

General Information

Submitter's Name:	BioMedix, Inc.
Address:	4205 White Bear Parkway St. Paul, MN 55110
Telephone:	651-762-4010
Contact Person:	Will Rogers or Dick Magnuson
Date Prepared:	July 23, 2004
Registration Number:	2134492

Device

Name:	PADnet Lab
Trade Name:	PADnet Lab
Common Name:	Plethysmograph
Classification Name:	Blood Flow Monitor
Product Code:	JOM
Class:	II
Regulation Number:	870.2780

Identification of Legally Marketed Devices

Name: Flostat Vascular Lab

K Number: K973644

Date Cleared: December 23, 1997

Description of the Device

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use in the early detection of peripheral vascular disease. The PADnet Lab has been tested to the following standards.

- EN60601-1 Electrical Safety
- EN60601-1-2 EMC
- ISO 10993-1 Biological evaluation

The BioMedix PADnet Lab is a non invasive cardiovascular blood flow monitor. It is intended for use by trained medical professionals in a hospital or clinic. It is not to be operated in an explosive atmosphere nor in the proximity to any equipment that has the potential to generate a sufficiently large electromagnetic field as to interfere in any manner with the operation of the PADnet Lab.

The BioMedix PADnet Lab is a Prescription Device, **not** life supporting or life sustaining, not an implant, supplied **non-sterile** with pressure cuffs. It requires a Personal Computer with the following requirements:

- Windows 2000 Operating System or higher
- 128 MB RAM
- 20 GB Free Hard Disk Space
- 600 MHz Processor or higher

Intended Use Statement

The BioMedix PADnet Lab is a non invasive device used to gauge the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures to assist in the identification of vascular disease. 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 use on or near non intact skin.

Components/ Part Numbers

Description	BioMedix Part Number
1- USB cable	100-1600
1- Cuff kit	7200
BioMedix PADnet Lab Software Program CD ROM	400-210
1-AC Power Cord	350-215
1- PADnet Lab Operators Manual	10650

Table of Comparisons

The following summary table of comparisons compares the new device (PADnet Lab) to the predicate device: Flowstat Vascular Lab.

#	Area	New Device: PADnet Lab	Predicate Device: Flowstat Vascular Lab	Same	Different
1	Pulse Volume Recording	Plethysmograph	Plethysmograph	X	
2	Segmental Pressure flow sensor	Oscillometric	Distal Flow Sensor		X
3	Patient Population	Male/Female Adult	Male/Female Adult	X	
4	Environment	Hospital or Clinic	Hospital or Clinic	X	
5	Power Source	AC converted to DC	AC converted to DC	X	
6	Weight	4 lbs.	26 lbs.		X
7	Data acquisition	Single site	Bilateral		X
8	Software Controls	Operator initiated	Operator initiated	X	
9	Size	12 1/2"W X 10" D X 3 " H	20 1/2" W X 17 3/4 " D X 7" H		X
10	Cuff Deflation Rate	3-5 mm Hg/Sec	3-5 mm Hg/Sec	X	

11	Operating Environment	0 to +40°C 15 - 90%	0 to +40°C 15 - 90%	X	
12	Storage Environment	-40 to +50° C 5-95%	-40 to +50° C 5-95%	X	
3	Safety Standards	Yes	Yes	X	
14	EMC	Yes	Yes	X	
15	Prescription Device	Yes	Yes	X	
16	Cuff Bladder Deflation	Automatic	Automatic	X	
17	Inflation Method	Automatic	Automatic	X	
18	Cuff Sizes	Multiple	Multiple	X	
19	Clinical Reports	Yes	Yes	X	
20	Printed Reports	Yes	Yes	X	
21	Supplied Non-Sterile	Yes	Yes	X	

Discussion of Similarities and Differences

The PADnet Lab and the Flowstat Lab have the following similarities:

- Pulse Volume Recording
- Patient Population
- Environment
- Power Source
- Software Controls
- Cuff Deflation Rate
- Operating Environment
- Storage Environment
- Safety Standards
- EMC
- Prescription Device
- Cuff Bladder Deflation
- Inflation Method
- Cuff Sizes
- Clinical Reports
- Printed Reports
- Supplied Non-Sterile

The differences, with comments, are the following:

- Segmental Pressure flow sensor – The PADnet Lab uses Oscillometric not distal flow sensor.
- Weight – PADnet Lab is significantly less.
- Data acquisition – PADnet Lab is single site not bilateral.
- Size – PADnet Lab is significantly smaller.

Thus, even though the PADnet Lab is not identical to the Flowstat Vascular Lab, we at BioMedix believe it should be granted substantial equivalence because:

- It has the same intended use as the predicate device.
- It has the same technical characteristics as the predicate device and does not raise any new types of safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2004

Biomedix, Inc.
c/o Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K042616
Trade Name: Biomedix PADnet Lab
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: September 22, 2004
Received: September 23, 2004

Dear Ms. Danielson:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K042616

Indications for Use

510(k) Number (if known): _____

Device Name: Biomedix PADnet Lab

Indications for Use:

The BioMedix PADnet Lab is a non invasive device used to record physiological data from the lower extremity arterial system using pulse volume recordings and oscillometric segmental systolic blood pressures for use by the Physician in the identification of vascular pathology. 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 use on or near non intact skin.

User Profile:
Patient Population: Male/Female, Adults
Environment of Use: Hospitals or Clinics

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 K042616

(Posted November 13, 2003)