January 11, 2018

MESI, Development of medical devices, Ltd.
% Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K172655
Trade/Device Name: ABPI MD
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: December 6, 2017
Received: December 6, 2017

Dear Elaine Duncan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172655

Device Name

ABPI MD, Automated ankle-brachial index measuring device

Indications for Use *(Describe)*

The ABPI MD system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).

The ABPI MD system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI) and pulse volume recording (PVR)/volume plethysmography in adults.

It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD.
It may also be used on patients with venous or arterial ulcers prior to application of compression therapy.
The ABPI MD system can be used on patients with unilateral lower limb amputation.
The ABPI MD system is intended to be used to spot-check patients.
The ABPI MD system provides information regarding patient risk.
The physician has the responsibility of making proper judgements based on this information.

Prescription Use: Federal law restricts the use of this device to sale by or on the order of the physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY - K172655

SUBMITTER:

Submitted on behalf of:

Company Name:	**MESI, development of medical devices, Ltd.**
Address:	**Letaliska cesta 3C** **1000 Ljubljana** **Slovenia, Europe**
Telephone:	**+386 1 620 34 87**
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by:	**Elaine Duncan, M.S.M.E., RAC** **President, Paladin Medical, Inc.** **PO Box 560** **Stillwater, MN 55082**
Telephone:	**715-549-6035**
Fax:	**715-549-5380**

CONTACT PERSON:	**Elaine Duncan**
DATE PREPARED:	**September 1, 2017**
TRADE NAME:	**ABPI MD**
COMMON NAME:	**Automated ankle-brachial pressure index measuring device**
CLASSIFICATION NAME:	**21 CFR 870.2780** **Hydraulic, Pneumatic, or Photoelectric Plethysmographs**
PRO CODE:	**JOM**

SUBSTANTIALLY EQUIVALENT TO: **K143152 TM-ABI System**
Cleared July 22, 2015

DESCRIPTION of the DEVICE:

The ABPI MD system, is an automated ankle brachial pressure index measuring device, the system includes the following components:

- ABPI measuring unit
- Arm cuff size M
- Left ankle cuff size M
- Right ankle cuff size M
- AC/DC power supply
- Tubes
- USB cable

- Instructions for use, Installation and User guide, Certificate of Calibration, Certificate of Conformity and Warranty
- Software installed on a computer

It is intended to measure a patient's Ankle Brachial Pressure Index (ABPI) and Ankle Brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography. This is done through an automated process. The operator places the three color coded cuffs on the right or left arm, and on each ankle as described in the instructions for use, and connects to the device. When connected, the operator clicks start button to begin measurement. The device will then automatically control the inflation & deflation of the cuffs and monitor variations in individual pressures to determine values to be used for the calculation of the ABI values for the both left and right of the patient.

INDICATIONS FOR USE:

The ABPI MD system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). The ABPI MD system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI) and pulse volume recording (PVR)/volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to application of compression therapy. ABPI MD system can be used on patients with unilateral lower limb amputation.
The ABPI MD system is intended to be used to spot-check patients. The ABPI MD system provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.
Prescription Use: Federal law restricts the use of this device to sale by or on the order of a physician.

BASIS OF SUBSTANTIAL EQUIVALENCE

The predicate a legally marketed device: TM-ABI System has same indication for use, intended use, same technology (oscillometric method), and same performances and effectiveness as the ABPI MD System (device under submission).

Differences

The only difference between the two devices is labeling (trade name, manufacturer's name and logo).

For purpose of this submission, ABPI MD was compared to TM-ABI (predicate device). A detailed comparison is given in the Table of Substantial Equivalence Determination for ABPI MD and TM ABI predicate device below.

Substantial Equivalence Determination Table

Device	TM-ABI system (predicate device)	ABPI MD (Device under submission)	Equivalence of features & characteristics
510(k) Number	K143152	TBD	
Indications for Use / Intended use	TM-ABI system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). TM-ABI system is intended for the rapid measurement of ankle-brachial pressure index (ABPI) or ankle-brachial index	ABPI MD system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). ABPI MD system is intended for the rapid measurement of ankle-brachial pressure index (ABPI) or ankle-brachial index	Identical

Substantial Equivalence Determination Table			
Device	**TM-ABI system (predicate device)**	**ABPI MD (Device under submission)**	**Equivalence of features & characteristics**
	(ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD It may also be used on patients with venous or arterial ulcers prior to application of compression therapy. TM-ABI system can be used on patients with unilateral lower limb amputation. The TM-ABI system is intended to be used to spot-check patients. The TM-ABI system provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information. Prescription Use: Federal law restricts the use of this device to sale by or on the order of a physician.	(ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to application of compression therapy. ABPI MD can be used on patients with unilateral lower limb amputation. The ABPI MD system is intended to be used to spot-check patients. The ABPI MD system provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information. Prescription Use: Federal law restricts the use of this device to sale by or on the order of a physician.	
Dimensions / weight	Width: 250 mm, Height: 730 mm, Depth: 200 mm, Weight: 0.60 kg	Width: 250 mm, Height: 730 mm, Depth: 200 mm, Weight: 0.60 kg	Identical
Power Supply	Output: 5V DC/3.0A. Battery type: rechargeable lithium polymer AC/DC converter 5V. Capacity: 2,300mAh, number of measurements per charge: 30	Output: 5V DC/3.0A. Battery type: rechargeable lithium polymer AC/DC converter 5V. Capacity: 2,300mAh, number of measurements per charge: 30	Identical
Display	4,3" color LCD screen with 16-bit color depth resolution: 480 x 272 pixels	4,3" color LCD screen with 16-bit color depth resolution: 480 x 272 pixels	Identical
Applied parts in contact with the patient	3 cuffs, tubes and bladders	3 cuffs, tubes and bladders	Identical
Materials	**ABS plastic** (Device Housing), **Silicon** (Tubes), **PU bladder, Nylon-Cotton protecting layer** (Pressure cuffs)	**ABS plastic** (Device Housing), **Silicon** (Tubes), **PU bladder, Nylon-Cotton protecting layer** (Pressure cuffs)	Identical

Substantial Equivalence Determination Table			
Device	**TM-ABI system (predicate device)**	**ABPI MD (Device under submission)**	**Equivalence of features & characteristics**
Testing Bench	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.	Identical
Measurement types	Right and left Ankle brachial pressure index : Left ABI = Left ankle pressure Arm pressure Right ABI = Right ankle pressure Arm pressure	Right and left Ankle brachial pressure index : Left ABI = Left ankle pressure Arm pressure Right ABI = Right ankle pressure Arm pressure	Identical
Measurement ranges	Pressures range : Diastolic 40 to 180mmHg Systolic 39 to 242 mmHg	Pressures range : Diastolic 40 to 180mmHg Systolic 39 to 242 mmHg	Identical
Limit values of measurement errors	Ankle brachial pressure index: ± 0.1	Ankle brachial pressure index: ± 0.1	Identical
Cuffs inflation and deflation	Automatic inflation using an air pump and deflation using an electromagnetic valve.	Automatic inflation using an air pump and deflation using an electromagnetic valve.	Identical
Pulse Volume / Plethysmography	Pneumo-plethysmography method using the cuffs measuring the blood pressure values : Plethysmography displayed at the inflammation and deflation pressure	Pneumo-plethysmography method using the cuffs measuring the blood pressure values : Plethysmography displayed at the inflammation and deflation pressure	Identical
Temperature and humidity range	Working environment: 10 to 40°C, 30 to 85% relative air humidity, IPX0 protection, transport and storage: 0 to 60°C, up to 85% relative air humidity.	Working environment: 10 to 40°C, 30 to 85% relative air humidity, IPX0 protection, transport and storage: 0 to 60°C, up to 85% relative air humidity.	Identical
Target population	Adult	Adult	Identical
Where used	Clinical environment	Clinical environment	Identical
PC Data transmission	USB	USB	Identical
ABI results: Coefficient of correlation r with the standard Doppler probe method	r= 0.88	r= 0.88	Identical

SUMMARY of TESTING:

The same testing and validation performed to qualify the TM-ABI is the testing for the ABPI MD, which includes:

Biocompatibility testing was performed in accordance to ISO 10993-1 “Use of International Standard ISO-10993, ‘’Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.’

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Electrical Standard tests were performed to evaluate its electromagnetic compatibility (EMC). Device was tested according to standards IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Test.

CONCLUSION:

The ABPI MD by MESI, Ltd. is identical to the predicate device. The ABPI MD device has the same indication for use, intended use as the TM-ABI predicate device, the same materials and technology as the predicate device, and utilizes the same manufacturing processes as the predicate device. The same test results apply to both devices, because MESI, d.o.o. is Original Equipment Manufacturer (OEM) of the predicate device (TM-ABI system) and manufacturer of the ABPI MD. The only difference between the TM-ABI predicate device and ABPI MD device is labeling of the device and distributor’s name and logo.