December 11, 2020

Mesi D.O.O.
Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K201046
Trade/Device Name: Automated ankle brachial pressure index measuring device, MESI mTABLET system
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: April 20, 2020
Received: April 21, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201046

Device Name

MESI mTABLET ABI, Automated Wireless ABI system

Indications for Use *(Describe)*

The MESI mTABLET ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).

MESI mTABLET ABI is intended for the rapid measurement of ankle-brachial pressure index (ABI) and pulse 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.

MESI mTABLET ABI can be used on patients with unilateral lower limb amputation.
The MESI mTABLET ABI is intended to be used to spot-check patients.
The MESI mTABLET ABI 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY # K201046

SUBMITTER on behalf of **MESI D.O.O**

Address: **Leskoskova cesta 11A**
1000 Ljubijana
Slovenia, Europe

Telephone: **+386 1 620 34 87**
Fax: **+386 8 2015 31 95**

by:

Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: **715-549-6035**

CONTACT PERSON: **Elaine Duncan, M.S.M.E., RAC, FAIMBE**

DATE PREPARED: **December 12, 2020**

TRADE NAME: **MESI mTABLET ABI**
COMMON NAME: **Automated ankle-brachial pressure index measuring device**
CLASSIFICATION NAME: **Hydraulic, Pneumatic, or Photoelectric Plethysmographs**
Regulation **870.2780**
CLASSIFICATION **Class II**
PRO CODE: **JOM**

SUMMARY of SUBSTANTIALLY EQUIVALENCE TO: ABPI MD, K172655

The MESI mTABLET ABI has the same indication for use and intended use as the ABPI MD predicate device, also manufactured by MESI D.O.O. Analysis of similarities and differences has shown that differences between the two products, primarily as a result of the use of the mTABLET and transmission of data to the tablet from the ABI cuffs, do not introduce new risks.

DESCRIPTION of the DEVICE: MESI mTABLET ABI is a medical device comprised out of three parts. Diagnostic modules with a tubeless cuff (ABISYS) that is attached to a patient upper arms and ankles, a medical grade tablet used to display the measurement (MTABSYSW) and a charging station (CS4SYS). It is used in a professional clinical environment by trained medical experts for diagnostic and screening purposes.

MESI mTABLET ABI is a device used for screening of Peripheral Arterial Disease (PAD). The measurement is performed non-invasively by measuring blood pressure in the brachial artery and pressures in the foot arteries (dorsalis pedis and the posterior tibial artery). After the blood pressures have been measured the MESI mTABLET ABI calculates the ration between higher of the two arm values and both ankles.

510(k) Summary-Continued

INDICATIONS FOR USE:

The MESI mTABLET ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). MESI mTABLET ABI is intended for the rapid measurement of ankle-brachial pressure index (ABI) and pulse 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. MESI mTABLET ABI can be used on patients with unilateral lower limb amputation.
The MESI mTABLET ABI is intended to be used to spot-check patients.
The MESI mTABLET ABI 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: ABPI MD has same indication for use, intended use, same technology (oscillometric method), and same performances and effectiveness as the MESI mTABLET ABI (device under submission).

Differences

The only differences between the two devices is use of the mTABLET and transmission of data to the tablet from the ABI cuffs. There are now 4 ABI tubeless cuffs with different fabric covering.

For purpose of this submission, MESI mTABLET ABI was compared to ABPI MD (predicate device), in the Table of Substantial Equivalence Determination.

	Substantial Equivalence Determination Table		
Feature	**ABPI MD**	**MESI mTABLET ABI**	**Analysis**
510(k) Number	K172655	K201046	
Manufacturer	MESI D.O.O.	MESI D.O.O.	same
Indications for Use / Intended use	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 (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.	The MESI mTABLET ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). MESI mTABLET ABI is intended for the rapid measurement of ankle-brachial pressure index (ABI) and pulse 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. MESI mTABLET ABI can be used on patients with unilateral lower limb amputation. The MESI mTABLET ABI is intended to be used to spot-check patients. The MESI mTABLET ABI 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.	Identical

510(k) Summary-Continued

	Substantial Equivalence Determination Table		
Feature	**ABPI MD**	**MESI mTABLET ABI**	**Analysis**
Dimensions / weight	Width: 250 mm, Height: 730 mm, Depth: 200 mm, Weight: 0.60 kg	mTABLET UNIT Width: 199 mm (7,83 inches), Depth: 278mm (10,95 inches), Height: 53mm (2,08 inches), Weight:757grams mTABLET WI-FI DOCKING UNIT Width: 176 mm (6,93 inches), Depth: 126 mm (4,96 inches), Height: 40 mm (1,57inches), Weight: 717grams TUBELESS CUFF UNIT (4x): Width: 40 mm (1.57 inches) Depth: 40 mm (1.57 inches) Height: 150 mm (5.91 inches) Weight: 286 g LARGE CHARGING PLATE UNIT: Width: 400 mm (15.75 inches), Depth: 200 mm (7.87 inches), Height: 38 mm (1.49 inches), Weight: 675 grams	NOTE 1
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	mTABLET UNIT AC/DC adaptor: FW8030M/05(FRIWO) Input: 100-240 V~; 50-60 Hz Output: 5 Vdc; 5000 mA Battery type: RechargeableLithium-Polymer battery(LP6058110) Capacity: 8800 mAh, Battery operation: more than 8 hours WIRELESS CUFF UNIT Battery type: Rechargeable Lithium-Polymer battery, Capacity: 1240 mAh Examinations per battery charge: > 200 Charge time for depleted battery (for each unit): approximately 1.5 hours (minimum charge time for 1 ABI measurement, with all units on the charging station : 10 minutes) LARGE CHARGING PLATE UNIT AC/DC adaptor: FW8030M/05 (FRIWO FOX30-XM) Input: 100-240 V~; 50-60 Hz Output: 5 Vdc / 5000 mA	NOTE 2
Display	4,3'' color LCD screen with 16-bit color depth resolution: 480 x 272 pixels	10,1" color IPS screen with 1280x800 resolution	NOTE 3
Applied parts in contact with the patient	3 cuffs, tubes and bladders	4x tubeless cuffs	NOTE 4

510(k) Summary-Continued

	Substantial Equivalence Determination Table		
Feature	**ABPI MD**	**MESI mTABLET ABI**	**Analysis**
Materials in contact with the patient	Silicon (Tubes), PU bladder, Nylon-Cotton protecting layer (Pressure cuffs)	TPU coated PU leather – outside layer Nylex based PU leather – inside layer TPU bladder	NOTE 5
Testing bench	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.	See list below	equivalent
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
Limit values of measurement errors	ABPI: Within ± 0.1	ABPI: Within ± 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, relative air humidity: 25 to 85% IP42 protection Transport and storage environment: -15° to 50°C (<1 month) / -15° to 40°C (<3 month) / -15° to 25°C (<12 month) Relative humidity: 25 to 85% (no condensation) IP42 protection	NOTE 6
Target population	Adult	Adult	Identical
Where used	Clinical environment	Clinical environment	Identical
PC Data transmission	USB	Cloud	NOTE 7
ABI results: Coefficient of correlation r with the standard Doppler probe method	r= 0.88	r= 0.88	Identical

510(k) Summary-Continued

NOTES to DIFFERENCES in COMPARATIVE ANALYSIS:

NOTE 1:
Predicate ABPI MD is all in one device system, with charging adaptor and cuffs connected to the main display unit. MESI mTABLET ABI is a system that uses a wireless connection between display unit (mTABLET UNIT) and TUBELESS CUFF UNITS (CUFFMD). The only dimension difference that would have a potential impact on the patient is the weight and size of the CUFFs. Since the patient is laying supine during testing, differences in cuff weights do not have an impact on patient comfort or usability.

NOTE 2:
MESI ABPIMD performs the ABI measurement only on battery power. The mTABLET UNIT uses a battery with bigger capacity (compared to predicate ABPI MD) which requires a different, more powerful power supply. WIRELESS CUFF UNITS are charged with a charging station with 4 charging ports (LARGE CHARGING PLATE UNIT). WIRELESS CUFF UNITS are charged all at once and require a more powerful power supply. The differences in power supply do not introduce new risks because the recharging of the batteries is not conducted while attached to the patient.

NOTE 3:
MESI mTABLET ABI system uses mTABLET UNIT as a display device whereas the predicate device display was incorporated into the main unit. mTABLET UNIT has a 10,1" touch-screen IPS screen which provides a better user experience and shows more details about measurements. The testing of the mTABLET has shown that this device is safe.

NOTE 4:
MESI mTABLET ABI has 4 cuffs instead of 3 cuffs as with the MESI ABPI. The one additional cuff provides users with the option to put all 4 cuffs on both legs and both arms at the same time. The MESI mTABLET ABI will perform simultaneous blood pressure measurement on both arms. The arm with the higher blood pressure is identified and used for the 3 cuff ABI measurement. The MESI ABPI MD has 3 cuffs which causes the users need to identify the arm with the higher blood pressure before performing the ABI measurement, or to perform the ABI measurement twice (once with each arm). Therefore, the system now provides 4 cuffs as a convenience to the user.

NOTE 5:
MESI mTABLET ABI system uses slightly different tubeless cuffs material compared to predicate ABPI MD. Biocompatibility testing shows there are no new risks from the different cuff material.

NOTE 6:
MESI mTABLET ABI is assembled of different components compared to predicate ABPI MD. This is the main reason why mTABLET ABI device has slightly different operating condition tolerances. The differences do not affect any risks.

NOTE 7:
Predicate device ABPI MD uses a USB connection to transfer measurement data to PC. MESI mTABLET ABI uses a Bluetooth connection to transfer measurement data from the WIRELESS CUFF UNIT to the mTABLET UNIT. Validation of performance has shown that this does not introduce new risks.

510(k) Summary-Continued

SUMMARY of TESTING and QUALIFICATION:

All applied parts or parts of CUFFSYS that come in direct contact with the patient have passed biocompatibility testing according to **EN ISO 10993-1 2009/AC:2010** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

EN ISO 15223-1:2016- Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Software documentation and review has complied with the US FDA ***Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices***; and ***Content of Premarket Submissions for Management of Cybersecurity in Medical Devices***
Guidance for Industry and Food and Drug Administration Staff; in addition to

EN IEC 62366 2008 Medical device software – Software life cycle
ISO 14971 2012 Medical devices - Application of risk management to medical devices
IEC 62304 2006/A1:2015 Medical device software – Software life cycle Processes

The following standardized testing has been performed:

IEC 60601-1 v1 2006/A1:2013 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 v1-2 2015 Medical electrical equipment – Part 1 – 2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and test

IEC 60601-1-6 2010/A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 80601-2-30 2-30 2010 Medical electrical equipment Part 2-30: Particular requirements form basic safety and essential performance of automated non-invasive sphygmomanometers

EN 303 446-1 2017 ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment

Wireless coexistence testing was performed per Tier 2 specifications of the ANSI/IEEE C63.27:2017 American National Standard for Evaluation of Wireless Coexistence.