July 28, 2023

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

Re: K223670
Trade/Device Name: MESI mTablet ECG Diagnostic System, MESI mTablet ECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 23, 2023
Received: June 27, 2023

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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223670

Device Name
MESI mTABLET ECG

Indications for Use *(Describe)*
The MESI mTABLET ECG is indicated for use on adult or pediatric patients, to evaluate and diagnose patient cardiac function.

MESI mTABLET ECG is intended to measure heart activity by ten (10) electrodes placed on the patient's body which measure miniscule electrical activity generated by the heart muscle depolarizations.

The MESI mTABLET ECG is solely used in professional clinical environment by trained healthcare personnel.
The MESI mTABLET ECG provides information regarding the patient's cardiac function.
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.

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510(k) Summary

Submitted on behalf of: MESI D.O.O

Date Prepared: July 28, 2023

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CONTACT PERSON: Elaine Duncan, MSME, RAC, FAIMBE
President, Paladin Medical, Inc.

Trade name	**MESI mTABLET ECG**
Common name	12-lead resting wireless ECG system
Classification name	Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Device classification	Class II
Product classification	870.2340
Product code	DPS
Classification panel	Cardiovascular

DEVICE DESCRIPTION

The MESI mTABLET ECG portable 12 lead resting ECG system is intended to screen cardiac abnormalities. The MESI mTABLET ECG System acquires, permits viewing and storing signals from adult and pediatric patients. The MESI mTABLET ECG is one of several variations of the company's MESI mTABLET system portfolio.

MESI mTABLET ECG is intended to measure heart activity by ten electrodes placed on the patient body which measure miniscule electrical activity generated by heart muscle depolarizations. This activity is captured and displayed on a graphical representation on the MESI mTABLET UNIT. The MESI mTABLET ECG supports acquisition of 10 seconds signal or manual mode with acquisition up to 5 minutes.

The MESI mTABLET ECG provides analytical statements when configured with the appropriate options. It also comes with Glasgow algorithm for automatic interpretation which offers diagnostic opinion to the user. This opinion is not intended to constitute professional advice, diagnosis or treatment, or be a substitute for professional judgment.

INDICATIONS FOR USE:

The MESI mTABLET ECG is indicated for use on adult or pediatric patients, to evaluate and diagnose patient cardiac function. MESI mTABLET ECG is intended to measure heart activity by ten (10) electrodes placed on the patient's body which measure miniscule electrical activity generated by the heart muscle depolarizations. The MESI mTABLET ECG is solely used in professional clinical environment by trained healthcare personnel. The MESI mTABLET ECG provides information regarding the patient's cardiac function. 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.

PREDICATE DEVICE and EQUIVALENCE:

The MESI mTABLET ECG has a similar indication for use and intended use as the **CARDIOLINE HD+** predicate device (**K150289**), manufactured by **Cardioline S.p.A.** In addition, the MESI mTABLET ECG is equivalent to the reference device "touchECG" **(K160746)** that is intended to be used in conjunction with CARDIOLINE HD+ device (K150289) that acquires the ECG signal and transmits it. The
"touchECG is a software medical device provided on a CD support. The touch ECG employs the Glasgow Algorithm for interpretation. The MESI mTABLET ECG is intended for spot-checking use.

Additionally, the **MESI mTABLET ABI** (**K201046**), manufactured by **MESI D.O.O** serves as a **reference device** to the basic technology of the tablet communication and several similar components, such as charging unit. Indeed, the MESI mTABLET ECG uses the same tablet device and charging plate as **MESI mTABLET ABI**, cleared under 510(k) number **K201046**.

Comparison of Technological Characteristics with Predicate and Reference Device

Substantial Equivalence Determination Table					
Device	**CARDIOLINE HD+**	**touchECG**	**MESI mTABLET ABI**	**MESI mTABLET ECG**	**Equivalence of features & characteristics**
510(k) Number	K150289	K160746	K201046	K223670	
Manufacturer	Cardioline S.p.A. Predicate	Cardioline S.p.A Reference	MESI D.O.O. Reference	MESI D.O.O. Subject Device	
Indications for Use / Intended use	HD+ is a physiological ECG acquisition module. HD+ transmits wireless, via Bluetooth to a PC or Tablet, the data acquired, without making any analysis or filtering on the data acquired. HD+ acquires 12-lead ECG waveforms meeting the standards for clinical and diagnostic applications (AAMI, ANSI, AHA, ACC) and offers full ECG acquisition. HD+ is designed to acquire and transmit a high quality ECG data allowing the patient to be free to moving (without cable connected to the processing unit). The HD+ transmits the acquired physiological signals in real-time to a computer/device where a compatible application is installed. All data acquired are sent via Bluetooth to a receiver that it can be a PC, tablet or device capable of receiving BT data.	touchECG is designed to check and diagnose cardiac function. However, a physician must validate the results of the analysis run by the ECG. touchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use by health professional in emergencies (ambulances). touchECG is intended to be used in conjunction with CARDIOLINE HD+ device. The device analyzes, displays and prints out electrocardiograms. The ECG's are acquired from CARDIOLINE HD+ device. The device interprets the data for review by a physician. The device must be used by a physician or by health professionals on behalf of an authorized doctor in clinical facilities. It is not intended as the only means for determining the diagnosis. The device's interpretation of the ECG	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 MESI mTABLET ECG is indicated for use on adult or pediatric patients, to evaluate and diagnose patient cardiac function. MESI mTABLET ECG is intended to measure hearth activity by ten (10) electrodes placed on the patient's body which measure miniscule electrical activity generated by the heart muscle depolarizations. The MESI mTABLET ECG is solely used in professional clinical environment by trained healthcare personnel for spot- checking. The MESI mTABLET ECG provides information regarding the patient's cardiac function. The	EQUIVALENT; MESI mTABLET ECG has same indication for use as the Cardioline and is also tablet and bluetooth based. Both can use 12 lead ECG electrodes Both are indicated for adult and pediatric patients. MESI mTABLET ECG uses the same technological platform as the MESI mTABLET ABI.

	The ECG is transmitted verbatim to the receiving system, without LSB or sampling adjustment. It is up to the receiving system/application to perform the necessary processing such as (but not limited to) LSB scaling, signal filtering, Resting ECG analysis etc. The device HD+ is intended to be used on adult and on all pediatric patients. The device is intended for use by qualified, trained nurses and physicians operating in hospitals, clinics and medical practices.	analysis is only significant if used together with an additional analysis by the physician and by an assessment of all the patient's important data. The device can be used on adults patients. The device must not be used as a physiological monitoring of vital signs. touchECGis intended to be used in conjunction with CARDIOLINE HD+ device (K150289 that acquires the ECG signal and transmits it. touchECG is a software medical device provided on a CD support	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.	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	Dimensions: 115 x 65 x 15 mm Weight: < 90 grams (including batteries)	The device installs on any PC, tablet or notebook with the minimum requisites shown below: Operating System - Windows 7, Windows 8.1, Windows 10 Processor - Intel I5 or higher RAM - 4GB or more Free space on Hard Disk - 3GB or more. Monitor - 640 x 480 pixel or more Bluetooth - Bluetooth 2.1 +EDR Printer - Laser (colour/BW) Printing paper: A4, Letter Interpretation Algorithm: Glasgow algorithm Additional applications - Email application which supports the EML format (only required for the email File	MESI mTABLET UNIT Width: 199 mm (7,83 inches), Depth: 278mm (10,95 inches), Height: 53mm (2,08 inches), Weight: 757grams MESI mTABLET WI-FI DOCKING UNIT Width: 176 mm (6,93 inches), Depth: 126 mm (4,96 inches), Height: 40 mm (1,57inches), Weight: 717grams MESI 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	MESI mTABLET UNIT Width: 199 mm (7,83 inches), Depth: 278mm (10,95 inches), Height: 53mm (2,08 inches), Weight: 757grams MESI mTABLET WI-FI DOCKING UNIT Width: 176 mm (6,93 inches), Depth: 126 mm (4,96 inches), Height: 40 mm (1,57inches), Weight: 717grams MESI ECG UNIT: Width: 40 mm (1.57 inches) Depth: 40 mm (1.57 inches) Height: 135 mm (5.31	MESI mTABLET dimensions IDENTICAL TO THE MESI mTABLET ABI Dimensional differences between MESI TUBELESS CUFF UNIT and MESI ECG UNIT due to internal hardware differences are insignificant

		Upload feature) It prints out in the following formats: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channel in automatic mode, and 3, 6 or 12 printout channels of the rhythm strip.	MESI 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	inches) Weight: 220 g MESI 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	
Power Supply	2x AAA standard 1,5 V batteries	Intrinsic to add on system	MESI 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 MESI TUBELESS CUFF UNIT Battery type: Rechargeable Lithium-Polymer battery, Capacity: 1240 mAh Examinations per battery charge: > Power Supply 2x AAA standard 1,5 V batteries Intrinsic to add on system MESI mTABLET UNIT	MESI 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 MESI ECG UNIT Battery type: Rechargeable Lithium-Polymer battery, Capacity: 1240 mAh Examinations per battery charge: > 2000 Charge time for depleted battery: approximately 2 hours (minimum charge time for 1 automatic mode ECG: 10 minutes) MESI LARGE CHARGING PLATE UNIT AC/DC adaptor: FW8030M/05	IDENTICAL TO THE MESI mTABLET ABI

			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 MESI TUBELESS CUFF UNIT Battery type: Rechargeable Lithium-Polymer battery, Capacity: 1240 mAh Examinations per battery charge: > MESI 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 MESI ECG UNIT Battery type: Rechargeable Lithium-Polymer battery, Capacity: 1240 mAh IDENTICAL TO THE MESI mTABLET ABI	(FRIWO FOX30-XM) Input: 100-240 V~; 50-60 Hz Output: 5 Vdc / 5000 mA	
Display	LCD color touch screen	various	10,1" color IPS screen with 1280x800 resolution	10,1" color IPS screen with 1280x800 resolution	IDENTICAL TO THE MESI mTABLET ABI
Applied parts in contact with the patient	Disposable electrodes, clamps	NONE	2x tubeless arm cuffs 2x ankle cuffs	Disposable electrodes	The user supplies the disposable electrodes
Materials in contact with the patient	Not specified	NONE	ARM CUFFS: TPU coated PU leather – outside layer Nylex based PU leather – inside layer TPU bladder	Requires user to supply disposable electrodes: Adhesive: Medical grade pressure sensitive adhesive Foam: Synthetic foam – Open	MESI mTABLET ECG uses disposable electrodes, which meet ISO 10993-1. Not supplied by MESI.

				cell; Connector: stainless steel	
Bench Testing	Applied parts: CF RF emissions: Group 2, Class B Compliant with standards: EC 60601-1 IEC 60601-2-25 IEC 60601-1-2 ETSI EN 300 328 ETSI EN 301 489 -1 ETSI EN 301 489 -17 ETSI EN 300 440 -2 FCC CFR47 Part 15 (US)	Defibrillation Protection Overload Tolerance Requirements for mplitude measurements Interval Measurements Requirements for interval measurements on biological ECGs Indication of Inoperable ECG Leads Minimum Lead Configuration Wilson Leads Input Impedance Required Gains Common Mode Rejection Line Filter Response Noise Level Channel Crosstalk High Frequency Response Low Frequency Response Linearity and Dynamic Range Sampling and Amplitude Quantization Record Identification Patient Identification Recording Speed Time and Amplitude Ruling Use with Cardiac Pacemakers	Type of protection against electric shock: Class II Applied parts: BF SoftWare classification: Class B RF emissions: Group 1, Class B Compliant with standards: EN 60601-1:2006/A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010/A1:2015 EN 80601-2-30:2010 EN ISO 15223-1:2016 EN 303 446-1:2017 EN 62366:2008 EN 62304:2006/A1:2015 EN ISO 10993-1:2009/AC:2010 EN ISO 14971:2012 IEEE/ANSI C63.27-2017	Type of protection against electric shock: Class II Applied parts: CF SoftWare classification: Class B RF emissions: Group 1, Class B Compliant with standards: EN 60601-1:2006/A1:2013 EN 60601-1-6:2010/A1:2015 EN 60601-2-25:2015 EN 62304:2006/A1:2015 EN 62366:2008 EN 60601-1-2:2015 EN ISO 15223-1:2016 EN 1064:2005/A1:2007 EN 303 446-1:2017 EN ISO 14971:2012 EN ISO 10993-1:2009/AC:2010 IEEE/ANSI C63.27-2017	MESI mTABLET ECG meets more ECG standards and better RF emisson compliance than Cardioline HD+. EMC and safety test reports are available in the Section 17 – Bench Testing. Test reports: T223-0126-20_60601-1 T251-0146-20_60601-1-2 T223-0127-20_60601-1-6 T223-0122-20_60601-2- 25 F2P27871A-03E
Temperature and humidity range	Working environment: Temperature between +10 and +40 °C inclusive, Relative humidity between 25 and 95 % inclusive (without condensation), Atmospheric pressure between 700 and 1060 mbar Transport and storage environment:		Working environment: 10° to 40°C, relative air humidity: 25 to 85% Transport and storage environment: -15° to 50°C (<1 month) /	Working environment: 10° to 40°C, relative air humidity: 25 to 85% Transport and storage environment: -15° to 50°C (<1 month) /	IDENTICAL TO THE MESI mTABLET ABI

	Temperature between -10 e +40°C inclusive Relative humidity between 25 and 95 % inclusive (without condensation) Atmospheric pressure between 500 and 1060 mbar inclusive		-15° to 40°C (<3 month) / -15° to 25°C (<12 month) Relative humidity: 25 to 85% (no condensation) IP42 protection	-15° to 40°C (<3 month) / -15° to 25°C (<12 month) Relative humidity: 25 to 85% (no condensation) IP44 protection	
Target population	Adults and pediatric patients	Adults	Adult	Adults and pediatric patients	IDENTICAL TO THE CARDIOLINE HD+
Where used	Clinical environment	Clinical environment	Clinical environment	Clinical environment	IDENTICAL
Leads connector	Single connector	Not applicable	/	Single connector	IDENTICAL TO THE CARDIOLINE HD+
A/D conversion	24 bit		/	24 bit	IDENTICAL TO THE CARDIOLINE HD+
Data resolution	20 bit, < 1uV/LSB		/	19 bit, 2,5 uV	MESI data resolution is slightly lower than Cardioline HD+ but both devices are high resolution ECGs and the MESI difference does not affect signal interpretaion.
Defibrilator protection	AAMI/IEC Standards		/	AAMI/IEC Standards	IDENTICAL TO THE CARDIOLINE HD+
Pacemaker detection	Hardware detection coupled with convolution digital filtering		/	Hardware detection coupled with convolution digital filtering (+/- 2 mV, 0,1 ms)	IDENTICAL TO THE CARDIOLINE HD+
Wireless system	Bluetooth 2.1 + EDR		Bluetooth 2.1 + EDR	Bluetooth 2.1 + EDR	IDENTICAL
Patient cable	10 wire single connector		/	10 wire single connector	IDENTICAL TO THE CARDIOLINE HD+
IP degree	IP 40 / IP 42 with silicon cover		IP 42	IP 44	MESI MTABLET ECG has higher IP degree than both predicate devices
ECG Interpretation	/	Glasgow Algorithm	/	Glasgow Algorithm	Same as the CARDIOLINE TOUCHECG

SUMMARY OF NON-CLINICAL TESTING:

In addition to conformance with requirements for software as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the following testing demonstrated conformity to appropriate safety and performance testing including cybersecurity.

IEC 60601-2-25- *Medical electrical equipment – Particular requirements for the basic safety and essential performance of electrocardiographs*
IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-6 *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
EN 303 446-1 *ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Requirements for equipment intended to be used in residential, commercial and light industry locations*
Wireless Coexistence Risk Analysis
IEEE/ANSI C63.27-2017 *American National Standard for Evaluation of Wireless Coexistence+ FDA Guidance documents*
IEEE/ANSI C63.27-2017
ANSI/AAMI EC53:2013 ECG trunk cables and patient leadwires

No clinical data is required to determine substantial equivalence.

CONCLUSION:

The MESI mTABLET ECG has a similar indication for use and intended use as the predicate device Cardioline HD+ (K150289). Both devices use a Bluetooth communication to transfer the acquired cardiac data from the ECG unit to another device where the waveforms are displayed. The only difference is in a few non-significant technical details the Cardioline HD+ (K150289) uses another type of electrodes – clamps – MESI mTABLET ECG only uses disposable electrodes. In addition, the MESI mTABLET ECG is equivalent to the "touchECG" that is intended to be used in conjunction with CARDIOLINE HD+ device (K150289) that acquires the ECG signal and transmits it. The "touchECG is a software medical device provided on a CD support. The touch ECG employs the Glasgow Algorithm for interpretation. The MESI mTABLET ECG is intended for spot-checking use.

The MESI mTABLET ECG uses the same tablet device and charging plate as the predicate device MESI mTABLET ABI (K201046), also manufactured by MESI D.O.O. Consequently, the MESI mTABLET ECG uses the same hardware and software for Wireless connection and the same charging equipment. Analysis of similarities and differences has shown that differences between the products do not introduce new or significant risks.

21 CFR 807.92: The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the predicate devices, and performs as well as or better than the legally marketed device identified.