March 2, 2026

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

Re: K251777
Trade/Device Name: MESI mTABLET SPIRO
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: January 29, 2026
Received: January 29, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

PRAKHYAT SINGH -S

Digitally signed by PRAKHYAT SINGH -S
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For

Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251777

Device Name
MESI mTABLET SPIRO

Indications for Use *(Describe)*
The MESI mTABLET SPIRO is indicated for use to conduct assessment of respiratory function by way of measurement of dynamic lung volumes (also known as spirometry) on adult and pediatric patients, ages 5 years and older. The device measures patient respiratory parameters including FVC, FEV1, FEV6, and VC. MESI mTABLET SPIRO is intended to be operated by medical professionals in health care environments including primary care facilities, hospitals and health centers.

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.

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Submitted on behalf of: MESI D.O.O

Date Prepared: March 2, 2026

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Contact Person:
Elaine Duncan, MSME., RAC, FAIMBE, FBSE
President, Paladin Medical, Inc.

Trade name	MESI mTABLET SPIRO
Common name	Automated wireless spirometry system
Classification name	Diagnostic spirometer.
Device classification	Class II
Product classification	868.1840
Product code	BZG
Classification panel	Anesthesiology**;** Spirometer, diagnostic

Predicate Device:	K212938: Vitalograph Model 6000 Alpha
Common Name:	Diagnostic Spirometer
Classification #:	868.1840
Regulatory Class:	II
Product Code:	BZG

Reference Device:	K201046: MESI mTABLET system
Common Name:	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic
Classification #:	870.2780
Regulatory Class:	II
Product Code:	JOM

Indications for Use

The MESI mTABLET SPIRO is indicated for assessment of respiratory function by way of measurement of dynamic lung volumes (also known as spirometry) on adult and pediatric patients, ages 5 years and older. The device measures patient spirometry parameters including FVC, FEV1, FEV6, and VC. MESI mTABLET SPIRO is intended to be operated by medical professionals in health care environments including primary care facilities, hospitals and health centers.

Device Description

The MESI mTABLET SPIRO is an automated wireless spirometer device for diagnosing and screening patients with respiratory diseases. The system is intended to perform, view and store spirometry measurements of adult and pediatric patients. It is comprised of a wireless tablet, spirometer module, disposable mouthpieces and charging station module.

The MESI mTABLET SPIRO is intended to be used in a professional clinical environment by trained healthcare personnel who understand the principle of spirometry measurements, can demonstrate the measurement procedure, verify that the system is working as intended, and start the measuring process.

The MESI mTABLET SPIRO works on pneumotach principle that relies on the airflow measurement according to the pressure difference that occurs when a flowing fluid is forced through a narrow section (disposable mouthpiece), resulting in a pressure decrease and a velocity increase, which is also known as the Venturi Effect. Values measured are indirectly calculated from the measured airflow. Spirometry parameters are captured and displayed as a numerical and graphical representation on MESI mTABLET UNIT.

The device is recharged through the AC/DC power supply. The MESI mTABLET SPIRO is not intended to be used while connected to mains electricity.

Substantial Equivalence Comparison

The MESI mTABLET SPIRO is compared to the predicate device, Vitalograph Model 6000 Alpha (K212938), a Class II diagnostic spirometer classified under 21 CFR 868.1840 (Product Code BZG). The predicate was selected because it has the same intended use, similar indications for use, and utilizes the same Fleisch pneumotachograph measurement principle for assessment of dynamic lung volumes. Both devices are intended for use by healthcare professionals in clinical environments to perform spirometry testing in adult and pediatric populations.

In addition to the primary predicate, the MESI mTABLET ABI (K201046) is referenced as a device-level technology platform to provide technological justification for the shared tablet hardware, wireless communication architecture, display system, and charging hardware. The MESI mTABLET SPIRO incorporates the identical tablet unit, Wi-Fi docking unit, and large charging plate previously cleared under K201046.

The substantial equivalence comparison between the MESI mTABLET SPIRO and the predicate device is summarized in the table below.

Device	6000 ALPHA	MESI mTABLET SPIRO	Comparison
510(k) Number	K212938 (Predicate Device)	K251777	
Manufacturer	Vitalograph Inc	MESI D.O.O.	
Indications for Use / Intended use	The intended use of the Vitalograph Model 6000 Alpha is the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry. The device measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC. The device is designed to be operated by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centers.	The MESI mTABLET SPIRO is indicated for use to conduct assessment of respiratory function by way of measurement of dynamic lung volumes (also known as spirometry) on adult and pediatric patients, ages 5 years and older. The device measures patient respiratory parameters including FVC, FEV1, FEV6, and VC. MESI mTABLET SPIRO is intended to be operated by medical professionals in health care environments including primary care facilities, hospitals and health centers.	Substantially equivalent to the predicate
Target population	Adults and pediatrics patients	Adults and pediatrics patients	Same as the predicate
Where used	Clinical environment	Clinical environment	Same as the predicate
Classification	21 CFR 868.1840 BZG	21 CFR 868.1840 BZG	Same as the predicate
Measurement technology	Fleisch Pneumotachograph type	Fleisch Pneumotachograph type	Same as the predicate

Device	6000 ALPHA	MESI mTABLET SPIRO	Comparison
510(k) Number	K212938 (Predicate Device)	K251777	
Manufacturer	Vitalograph Inc	MESI D.O.O.	
Volume calculation	Flow integration sampling 100Hz	Flow integration sampling 800Hz	Same as the predicate but at higher sampling rate
Maximum displaced volume	10L	14L	MESI mTABLET SPIRO can displace bigger air volume. The difference does not introduce any new risks.
Performance Specification	Accuracy: ±2.5% Not Publicly Available Not Publicly Available Not Publicly Available	Accuracy: ± 2.5% Repeatability: ±2.5% Linearity: ±2.5% Impedance: within 0.15 kPa/(L/s)	Similar as the predicate, within ATS 2019 guidelines.
Parameters measured	FVC, FEV1, FEV6, PEF, MVV and VC	FVC, FEV1, FEV6, and VC.	Similar parameters
Patient Interface	Flowhead cone	MESI spirometer UNIT and disposable mouthpiece	Substantially equivalent
Power Supply	7.2V, 2.2Ahr NiMH	MESI mTABLET UNIT AC/DC adaptor: Input: 100-240 V~; 50-60 Hz Output: 5 Vdc; 5000 mA Battery type: Rechargeable Lithium-Polymer battery Capacity: 8800 mAh, Battery operation: more than 8 hours MESI SPIRO UNIT	Similar battery type, Identical to MESI mTABLET ABI reference device

Device	6000 ALPHA	MESI mTABLET SPIRO	Comparison
510(k) Number	K212938 (Predicate Device)	K251777	
Manufacturer	Vitalograph Inc	MESI D.O.O.	
		Battery type: Rechargeable Lithium-Polymer battery, Capacity: 620 mAh Examinations per battery charge: > 150	
Display	Color touchscreen	10,1" color IPS screen with 1280x800 resolution	Identical to the MESI mTABLET ABI
Contact type and duration – Bio-compatibility	Externally Communicating, Limited Duration Tissue and Surface Contact, Skin / Mucosa,	Externally Communicating, Limited Duration Tissue and Surface Contact, Skin / Mucosa,	Same
Performance Testing	ATS/ERS (2019) ISO 23747:2007 ISO 26782:2009	ATS/ERS2019 ISO 26782:2009	MESI mTABLET SPIRO is compliant with applicable standards. The difference does not introduce any additional risks.
Electrical Safety and EMC	ES 60601-1 IEC 60601-1-2	ES 60601-1 IEC 60601-1-2:2014	Same as predicate
Working environment	Temperature: 10–40°C	Temperature: 10–40°C Humidity: 25% to 85%	Substantially Equivalent
Transport and storage environment	Not Available	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)	Same as Mesi mTABLET ABI

Device	6000 ALPHA	MESI mTABLET SPIRO	Comparison
510(k) Number	K212938 (Predicate Device)	K251777	
Manufacturer	Vitalograph Inc	MESI D.O.O.	
Communications	USB, Ethernet, WiFi	Bluetooth, WiFi	Identical to the MESI mTABLET ABI
IP degree	IP42	IP 30	MESI mTABLET SPIRO has slightly lower IP degree from the predicate and MESI mTABLET ABI.The difference does not introduce any risks.

Discussion of Differences

The MESI mTABLET SPIRO has the same intended use and similar indications for use as the Vitalograph Model 6000 Alpha (K212938), and both devices utilize a Fleisch pneumotachograph measurement principle for assessment of dynamic lung volumes. However, several technological differences exist that have been justified. The subject device employs a wireless, tablet-based architecture with Bluetooth and Wi-Fi connectivity, whereas the predicate is a standalone spirometer platform. The MESI mTABLET SPIRO samples flow data at a higher integration rate (800 Hz versus 100 Hz), supports a greater maximum displaced volume (14 L versus 10 L), and measures a more limited set of parameters (FVC, FEV1, FEV6, and VC) compared to the predicate, which also reports PEF and MVV. Additional differences include system configuration, power supply, user interface, and environmental protection ratings. These differences relate to hardware design, data acquisition rate, and feature set rather than to the fundamental measurement principle or intended diagnostic function. Based on performance testing and non-clinical validation, these differences do not raise new or different questions of safety or effectiveness.

Non-Clinical Testing

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
The patient contacting materials (Externally Communicating, Limited Duration Tissue and Surface Contact, Skin / Mucosa, were evaluated using: ISO 10993-5 (2009) – Cytotoxicity; ISO 10993-10 (2010) – Sensitization and Irritation; ISO 10993-18 (2020) – Chemical Characterization; ISO 18562-2 (2017) – Particulate Materials; ISO 18562-3 (2017) – Volatile Organic Compounds (VOC), with a toxicological risk assessment. The materials were found to be acceptable for their intended use.

Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the subject device. The system complies with AAMI ANSI ES 60601-1:2005 + A1:2012 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility – Requirements and Tests. In addition, wireless coexistence testing was performed in accordance with ANSI/IEEE C63.27:2017, consistent with the device's AAMI TIR69 risk assessment to evaluate the performance of the Bluetooth communication link in the presence of intentional and unintentional RF interference

Software Verification and Validation Testing
Software verification and validation testing were conducted per FDA Guidance on Content of Premarket Submissions for Device Software Functions. The documentation level for the software for this device was considered "Basic".
Cybersecurity testing and documentation conform to FDA Guidance on Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions.

Spirometry Performance
Performance testing per ATS/ERS (2019) for peak flow and timed forced expired volume per ISO 26782:2009 – Respiratory Equipment – Spirometers Intended for the Measurement of Forced Expired Volumes in Humans was performed.

Mechanical, Animal, and Clinical Testing
Reprocessing validation testing was conducted on the reusable aluminum housing in accordance with FDA's *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* guidance and AAMI ST98. No animal or clinical testing was performed

Substantial Equivalence Conclusion
The performance testing has demonstrated that the subject device has met the applicable standard performance requirements. Through a comparison of performance testing, design and features, and non-clinical testing, the subject device and predicate are found to be substantially equivalent.