April 23, 2026

Smwmed Inc.
% Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252389
Trade/Device Name: Rhythm Master ECG Patch (HM-15BB-AX, HM-15BW-AX, HM-15BW-DX)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: July 29, 2025
Received: July 31, 2025

Dear Youshan Gong:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JENNIFER W. SHIH -S

Jennifer 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252389

Device Name
Rhythm Master ECG Patch (HM-15BB-AX, HM-15BW-AX)

Indications for Use *(Describe)*
It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. It is intended for use by patients 18 years or older.

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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K252389 510(k) Summary

I. Submitter

Company name: Smwmed Inc.
Address: 9920 Pacific Heights Blvd Ste 410, San Diego CA 92121, United States of America
Contact person: Bo Pi
Title: CEO
Tel: +1 760 803 9092
Email: bosmwmed@smwmed.com
Date: April 22, 2026

II. Subject Device

Name of Device: Rhythm Master ECG Patch
Model(s): HM-15BB-AX, HM-15BW-AX
Regulatory Class: II
Common Name: recorder, magnetic tape, medical
Regulation Name: Medical Magnetic Tape Recorder
Regulation Number: 870.2800
Product Code: DSH
Review Panel: Cardiovascular

III. Predicate Devices

No.	Manufacturer	Device name	Product code	510(k) Number	Cleared Date
1.	Wellysis Corp.	S-Patch Ex Wearable ECG Patch	DSH	K231289	08/30/2023
2.	Braemar Manufacturing, LLC	ePatch®	DSH	K171410	01/04/2018

IV. Device Description

The Rhythm Master ECG Patch is a lightweight, compact cardiac monitoring device designed for continuous ECG recording for up to 3 days for the HM-15BB-AX model while the HM-15BW-AX can record for 7 days. This Type CF cardiac floating device features high-precision ECG monitoring with a dynamic range of ±10mV and excellent signal quality with a frequency response of 0.5-40Hz for HM-15BB-AX, HM-15BW-AX.

The device weighs only 6.8 grams and measures 37.0x22.5x7.7mm, making it comfortable for extended wear. The device is powered by a rechargeable 3.6V lithium-ion battery and HM-15BB-AX utilizes Bluetooth Low Energy technology for seamless data transmission to smartphones, HM-15BW-AX utilizes Type-C cable for seamless data transmission to computers. The device does not provide and is not intended for automated ECG analysis and/or use with third party analysis software. The device is not intended for real time monitoring.

The Rhythm Master ECG Patch is intended to be only applied and initialized by healthcare professionals prior to the patient wearing period. The patients can then wear the patch in home

environment. Before patients use the device in home setting, they shall receive training from healthcare professionals regarding the device intended use, contraindications, warnings and cautions with the device use.

The device offers signal processing mode: AC ECG channel. The AC ECG channel focuses on processing the dynamic components of ECG signals, enhancing the dynamic parts of the signal through a series of signal conditioning steps while filtering out unwanted baseline drift, making it suitable for routine ECG monitoring scenarios.

Specific device features:
Heart Rate (HR): The device provides a calculated heart rate value as a derived parameter obtained from the detection of QRS complexes in the acquired ECG signal. It is intended solely for general reference and long- term trend observation, offering a summary indication of average heart rate over the recording period.
Heart Rate Variability (HRV): HRV is a secondary, computed parameter derived from the time intervals between successive QRS complexes (RR intervals). It provides a quantitative indication of variations in heart rate over time and is displayed for general reference and trend observation only. The HRV value is not intended for diagnostic or interpretive purposes.
Accelerometer (ACC): The ACC waveform provides motion reference data to allows users and physicians to understand whether the patient is in motion or at rest for reference to signal quality. It is for reference only and has no diagnostic function.
Viewing of ECG: The device allows for the viewing of recorded ECG waveforms on a paired mobile application or PC software. This is the primary functionality that enables a qualified healthcare professional to perform diagnostic interpretation.

The above mentioned specific device features are standard features in modern ambulatory ECG monitoring devices and are verified to comply with IEC 60601-2-47 requirements as evidence for substantial equivalence.

V. Comparison of Intended use/ Indications for Use With the Predicate Device

It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. It is intended for use by patients 18 years or older. This intended use is similar to the predicate devices. Therefore, the Rhythm Master ECG Patch may be found substantially equivalent to its predicate devices.

VI. Comparison of Technological Characteristics With the Predicate Device

The Rhythm Master ECG Patch has the same intended use as the predicate devices. The technological characteristics, features, specifications, materials are similar to the predicate devices. Any minor differences between the subject device and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use.
Therefore, the Rhythm Master ECG Patch may be found substantially equivalent to its predicate devices.

	Subject device	Primary predicate device	Predicate device 1	Remark
K number	**K252389**	**K231289**	**K171410**	/
Trade name	Rhythm Master ECG Patch	S-Patch Ex Wearable ECG Patch	ePatch®	/
Manufacturer	Smwmed Inc.	Wellysis Corp.	Braemar Manufacturing, LLC	/
Model	HM-15BB-AX HM-15BW-AX	S-Patch Ex	ePatch®	/
Device Classification Name	Medical Magnetic Tape Recorder	Medical Magnetic Tape Recorder	Medical Magnetic Tape Recorder	Same
Review panel	Cardiovascular	Cardiovascular	Cardiovascular	Same
Regulation number	21 CFR 870.2800	21 CFR 870.2800	21 CFR 870.2800	Same
Device class	II	II	II	Same
Product code	DSH	DSH	DSH	Same
Indication for use/ Intended use	It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. Rhythm Master ECG Patch is intended for use by patients 18 years or older.	S-Patch Ex wearable ECG patch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue,chest pain and/or anxiety. S-Patch Ex wearable ECG patch is intended for use by patients 18 years or older.	The ePatch® is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The ePatch® is intended for use by adolescents 18-21 and adults.	Same
Location for use	Prescription Use	Prescription Use	Prescription Use	Same
Target population	patients 18 years or older.	S-Patch Ex wearable ECG patch is intended for use by patients 18 years or older.	The ePatch® is intended for use by adolescents 18-21 and adults.	Same
Single Use	Reusable / Rechargeable Monitor; Single Use Electrodes	S-Patch Ex is multi-patient, multi-use; compatible 3rd-party ECG electrode is single use	Reusable / Rechargeable Monitor, Single Use Electrodes	Same
Intended Use	Home & Healthcare settings	Home & Healthcare settings	Home & Healthcare settings	Same

	Subject device	Primary predicate device	Predicate device 1	Remark
K number	**K252389**	**K231289**	**K171410**	**/**
Environment				
Measured Parameters	Yes	Yes	Yes	Same
ECG Dynamic Range	-10mV to + 10mV	-10mV to + 10mV	-10mV to + 10mV	Same
Applied Part Category	Type CF (cardiac floating)	Type CF (cardiac floating)	Type BF (body floating)	Same
Battery	LIR1654 3.6V 110mAh Rechargeable lithium-ion button battery	DC 3V, Coin Battery (CR2032) - 100 hours	DC3.7V, rechargeable lithium-ion polymer battery – 48 hours Nominal voltage: 3.7V Charging voltage: 4.2V Capacity: Typical 350 mAh	Different
Data Stored and Transfer	Yes	Yes	Yes	Same
Communication Protocol	HM-15BB-AX: Bluetooth Low Energy (2402MHz – 2480 MHz) HM-15BW-AX: USB2.0	Bluetooth Low Energy (2402 – 2480 MHz)	USB 2.0	Same
Viewing Software Platform	HM-15BB-AX: Android APP HM-15BW-AX: Windows APP	A compatible 3rd-party ECG viewing software	Compatible 3rd party ECG viewing software including Cardiologs	Different
Data Encryption	Huffman Encoding encryption	Advanced Encryption Standard-CCM mode	Not publicly available	Different
Type of ECG Recorder	Patch	Not publicly available	Patch	Same
Number of ECG Channels	1	Not publicly available	1, 2 or 3	Same
Wear Time	Up to 7 days The two models use the same medical electrode patch which can be used up to 7 days, since the patch is for single use, the actual wear time for each specific model shall correspondent to its recording	Not publicly available	Up to 5 days	Similar

	Subject device	Primary predicate device	Predicate device 1	Remark
K number	**K252389**	**K231289**	**K171410**	**/**
	period.			
Recording Period	HM-15BB-AX: Up to 3 days HM-15BW-AX: Up to 7 days	No related information	Up to 9 days	Similar
Recording Format	Continuous	Not publicly available	Continuous	Same
Sensor Dimensions	37.0x22.5x7.7（H）mm	Not publicly available	10 x 40 x 49mm	Different
Sensor Weight	6.8 grams	Not publicly available	16 grams	Different
Frequency Response	0.5-40Hz	Not publicly available	0.05-215 Hz	Similar
Input Impedance	>10GOhms	Not publicly available	>10MOhms	Different
Resolution	15bit	Not publicly available	12 bit or 16 bit, depending on customer preference	Similar
Recording Standard	Holter	Not publicly available	Holter	Same
Patch Placement	Left chest, a finger's distance below the clavicle, tilted toward the left nipple at a 30-45° degree	Not publicly available	Sternum or appropriate position on torso	Same
Heart rate measurement function	Yes for model HM-15BB-AX. Measurement range: 30-200bpm Accuracy of heart rate measurement: ±2	Not publicly available	Not publicly available	Different
Heart Rate Variability (HRV) function	Yes	Not publicly available	Not publicly available	Different
Accelerometer (ACC) function	Yes	Not publicly available	Not publicly available	Different
Viewing of ECG waveform	Yes	Not publicly available	Yes	Same

	Subject device	Primary predicate device	Predicate device 1	Remark
K number	**K252389**	**K231289**	**K171410**	**/**
Signal processing mode	AC ECG channel	Not publicly available	Not publicly available	Different
Defibrillation-proof	No	Not publicly available	No	Same
Performance Standard	IEC 60601-1 IEC 60601-1-2, IEC 60601-4-2 IEC 60601-1-11 IEC 60601-2-47 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 Cybersecurity assessment and testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 Cybersecurity assessment and testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-47 ISO 10993-1	Same

VII. Performance Data

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Rhythm Master ECG Patch was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety

- 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 60601-1-11, Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- IEC 60601-2-47, Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 62133-2, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

3) Software Verification and Validation

Software documentation consistent with Basic documentation level was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement

specifications are met and all software hazards have been mitigated to acceptable risk levels. The following testing was performed to, and passed:

- IEC 62304, Medical device software - Software life cycle processes
- FDA's Guidance for Industry and FDA Staff, Content of Premarket Submissions for Device Software Functions

4) Cybersecurity

Cybersecurity assessment and testing were conducted, according to FDA's Guidance for Industry and FDA Staff, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

5) ECG Electrodes performance test

ECG Electrode was performed according to FDA Standard

- ANSI/AAMI EC12:2000 (R2020) Disposable ECG Electrodes

6) Energy Reduction

Energy reduction test was performed according to the test method of IEC 60601-1 Clause 8.5.5.2. The device was tested and demonstrated to be safe in case of defibrillation. However, the device is not defibrillation-proof.

7) Wireless coexistence test

Wireless coexistence test was performed according to ANSI/USEMCSC C63.27:2021 and ANSI TIR 69:2017/(R) 2020.

8) Human Factors and Usability

Usability test were performed according to FDA guidance. - Applying Human Factors and Usability Engineering to Medical Device

9) Patch attachment position

The Patch attachment position test was performed according to the internal criteria.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is substantially equivalent to the selected predicate devices.