August 30, 2023

Wellysis Corp.
% Nikki Batista
Vice President
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K231289
Trade/Device Name: S-Patch Ex Wearable ECG Patch
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: August 2, 2023
Received: August 3, 2023

Dear Nikki Batista:

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)*
K231289

Device Name
S-Patch Ex Wearable ECG Patch

Indications for Use *(Describe)*
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.

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.

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510(k) Summary

1. Date Prepared

August 02, 2023

2. Submitter's Information

- Name of Manufacturer: Wellysis Corp.
- Address: 8F, 425 Teheran-ro, Gangnam-gu, Seoul, Republic of Korea
- Contact Name: DoGyun Im
- Telephone No.: +82 10-9140-8475
- Email Address: Ian.Im@wellysis.com

3. Trade Name, Common Name, Classification

510(k) Number	K231289
Trade/Device/Model Name	S-Patch Ex
Product Name	S-Patch Ex ECG Patch System
Device Classification Name	Medical magnetic tape recorder
Regulation Number	21 CFR 870.2800
Classification Product Code	DSH
Device Class	II
510(k) Review Panel	Cardiovascular

4. Identification of Predicate Device(s)

The identified predicate device within this submission is shown as following:

Predicate Device

510(k) Number	K171410
Trade/Device/Model Name	ePatch®
Device Classification Name	Medical magnetic tape recorder
Regulation Number	21 CFR 870.2800

Classification Product Code	DSH
Device Class	II
510(k) Review Panel	Cardiovascular

5. Description of the Device

The S-Patch Ex ECG Patch System ("S-Patch Ex") is a light-weight electrocardiogram ("ECG") data collection device.

The S-Patch Ex operates wirelessly, and due to its compact size, it is unobtrusive during daily activity. The S-Patch Ex continuously acquires ECG signals and wirelessly transmits the data and via a smartphone application (that meets the definition of MDDS) to a compatible 3rd-party cloud-based ECG viewing platform for further analysis and interpretation by qualified medical professionals. The S-Patch Ex does not include but works with 3rd-party lithium coin batteries and 3rd-party ECG electrodes.

The S-Patch Ex is intended to be used by medical professionals in accordance with the User Manual. The S-Patch Ex can be worn by a patient in either a healthcare setting or at home. Certain actions (such as replacement of the electrodes) can be performed by the patient at the direction of a medical professional and in accordance with the User Manual.

6. Indications for use

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.

7. Intended use

The S-Patch Ex wearable ECG patch is an electrocardiography (ECG) data recording device for use by healthcare professionals for continuous collection of the ECG data at home and in healthcare settings.

The data recorded by the S-Patch Ex wearable ECG patch can be uploaded wirelessly via a smartphone application to a compatible 3rd-party cloud-based ECG viewing platform for further analysis and interpretation by qualified clinicians.

The S-Patch Ex wearable ECG Patch does not include automated ECG analysis and is not intended to be used with 3rd party automated ECG analysis software.

8. Comparison of the Technological Characteristics with the Predicate Devices

In comparison to the predicate device, the subject device provides similar indications for use, functions and technological characteristics and device performance. A tabular high-level comparison of the subject device and the predicate device is provided in table below. The S-Patch Ex ECG Patch System is substantially equivalent to its predicate device.

		Predicate Device	Subject Device
K Number		K171410	K231289
Manufacturer		Braemar Manufacturing, LLC	Wellysis Corp.
Product Name		ePatch®	S-Patch Ex ECG Patch System
Review Panel		Cardiovascular	Cardiovascular
Regulation Number		21 CFR 870.2800	21 CFR 870.2800
Product Code		DSH	DSH
Indications for Use		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 Patch® is intended for use by adolescents 18-21 and adults.	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.
Intended Patient Population		The ePatch® is intended for use by adolescents 18-21 and adults.	General care patients who are 18 years or older
Single Use		Reusable / Rechargeable Monitor, Single Use Electrodes	S-Patch Ex is multi-patient, multi-use; compatible 3rd-party ECG electrode is single use
Intended Use Environment		Home & Healthcare settings	Home & Healthcare settings
Measured	**ECG**	X	X

Parameters		
ECG Dynamic Range	-10mV to + 10mV	-10mV to + 10mV
Applied Part Category	Type BF (body floating)	Type CF (cardiac floating)
Battery	DC3.7V, rechargeable lithium-ion polymer battery – 48 hours	DC 3V, Coin Battery (CR2032) - 100 hours
Data Storage and Transfer	X	X
Communication Protocol	USB 2.0	Bluetooth Low Energy (2402 – 2480 MHz)
Viewing Software Platform	Compatible 3rd party ECG viewing software including Cardiologs	A compatible 3rd-party ECG viewing software
Data Encryption	No related information	Advanced Encryption Standard-CCM mode

9. Performance Data

Verification and validation activities established the safety and performance characteristics of the proposed subject device with respect to the predicate device. The following performance data demonstrated conformance with special controls and substantial equivalence to the predicate device's performance.

Biocompatibility Testing

Biocompatibility testing was conducted, included in-vitro cytotoxicity, irritation and sensitization, according to the recommendations of ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing.

Device Reuse and Cleaning Validation

The S-Patch Ex can be used on multiple patients. Low-level disinfection is required between patient usage and the low-level disinfection method was satisfactorily evaluated and did not raise any new or different questions of safety or effectiveness.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the S-Patch Ex. The subject device complies with the electrical safety and electromagnetic compatibility requirements established by the following standards.

Standards No.	Standards Organization	Standard Title	Version
60601-1	AAMI/ANSI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety	ES60601-1: 2005(R)201

Standards No.	Standards Organization	Standard Title	Version
		and Essential Performance (IEC 60601-1:2005, MOD)	2 and A1:2012
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02
60601-1-11	IEC	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	60601-1-11 Edition 2.0 2015-01

Firmware/Software Verification and Validation Testing

The S-Patch Ex contains "moderate" level of concern firmware/software because a failure or latent flaw could lead to a minor injury to the patient through incorrect information or through the action of the healthcare providers. Software verification and validation testing was conducted, and documentation is 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*, issued on May 11, 2005.

Integration and System Performance Testing

Multiple system performance testing was successfully performed, demonstrating comparative performance against traditional multi-leads ECG monitors and acceptable electrode placement performance. An integration testing was also conducted, demonstrating good ECG signal quality and compatibility with 3rd-party ECG viewing platforms.

Cybersecurity Assessment and Testing

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*, issued on October 2, 2014.

Animal Study

Animal performance testing was not required for this device.

Human Factors Usability Validation Study

A human factors summative usability validation study was conducted, according to FDA's Guidance for Industry and FDA Staff, *Applying Human Factors and Usability Engineering to Medical Devices*, issued on February 3, 2016.

Clinical Study

Clinical study was not required for demonstrating substantial equivalence to the predicate device.

10. Conclusion

The subject device S-Patch Ex ECG Patch System is substantially equivalent in indications for use, functions, and performance to the predicate device. The minor difference between subject and predicate device in single versus multiple patient usage was adequately evaluated and did not raise any new or different questions regarding its performance when used as labeled.

The verification and validation testing data supported the substantial equivalence and demonstrated that the subject device performs as intended in the specified use conditions.

Therefore, the S-Patch Ex ECG Patch System is substantially equivalent to the predicate device.