



February 16, 2024

Wellysis Corp.
Sam Engelman
Senior Manager, Digital Health Regulatory Affairs
8F, 425 Teheran-ro, Gangnam-gu
Seoul, 06159
South Korea

Re: K233906
Trade/Device Name: S-Patch (S-Patch ExL)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: January 19, 2024
Received: January 19, 2024

Dear Sam Engelman:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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 Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
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Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233906

Device Name

S-Patch (S-Patch ExL)

Indications for Use (Describe)

S-Patch ExL 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 ExL 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.

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510(k) Summary

1. Date Prepared

November 17, 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	K233906
Trade/Device/Model Name	S-Patch ExL
Product Name	S-Patch ExL ECG Patch System
Device Classification Name	Electrocardiograph, Ambulatory (Without Analysis)
Regulation Number	21 CFR 870.2800
Classification Product Code	MWJ
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	K231289
Trade/Device/Model Name	S-Patch Ex
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 ExL ECG Patch System ("S-Patch ExL") is a light-weight electrocardiogram ("ECG") data collection device.

The S-Patch ExL operates wirelessly, and due to its compact size, it is unobtrusive during daily activity. The S-Patch ExL 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 ExL does not include but works with 3rd-party lithium coin batteries and 3rd-party ECG electrodes.

The S-Patch ExL is intended to be used by medical professionals in accordance with the User Manual. The S-Patch ExL 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.

The S-Patch ExL should be worn continuously with the same electrodes for no more than 72 hours. At 72 hours, the existing electrodes should be removed and exchanged for new electrodes before continuing to collect ECG data.

6. Indications for use

S-Patch ExL 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 ExL wearable ECG patch is intended for use by patients 18 years or older.

7. Intended use

The S-Patch ExL 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 ExL 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 ExL 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 ExL ECG Patch System is substantially equivalent to its predicate device.

	Predicate Device	Subject Device
K Number	K231289	K233906
Manufacturer	Wellysis Corp.	Wellysis Corp.
Product Name	S-Patch Ex ECG Patch System	S-Patch ExL ECG Patch System
Review Panel	Cardiovascular	Cardiovascular
Regulation Number	21 CFR 870.2800	21 CFR 870.2800
Product Code	DSH	MWJ
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.	S-Patch ExL 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 ExL wearable ECG patch is intended for use by patients 18 years or older.
Intended Patient Population	General care patients who are 18 years or older	General care patients who are 18 years or older
Single Use	S-Patch Ex is multi-patient, multi-use; compatible 3 rd -party ECG electrode is single use	S-Patch ExL is multi-patient, multi-use; compatible 3 rd -party ECG electrode is single use

		Predicate Device	Subject Device
Intended Use Environment		Home & Healthcare settings	Home & Healthcare settings
Measured Parameters	ECG	X	X
ECG Dynamic Range		-10mV to + 10mV	-10mV to + 10mV
Applied Part Category		Type CF (cardiac floating)	Type CF (cardiac floating)
Battery		DC 3V, Coin Battery (CR2032) - 100 hours	DC 3V, Coin Battery (CR2450) - 216 hours
Data Storage and Transfer		X	X
Communication Protocol		Bluetooth Low Energy (2402 – 2480 MHz)	Bluetooth Low Energy (2402 – 2480 MHz)
Viewing Software Platform		A compatible 3 rd -party ECG viewing software	A compatible 3 rd -party ECG viewing software
Data Encryption		Advanced Encryption Standard-CCM mode	Advanced Encryption Standard-CCM mode
Battery Side Enclosure Size		30mm x 6mm	35.6mm x 8.7 mm
Weight		9 g	11 g

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 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 ExL 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 ExL. 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 and Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1:2005(R)2012 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 ExL contains “moderate” level of concern firmware 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. However, the subject device uses the same firmware as the predicate device (K231289). Therefore, no additional firmware/software verification and validation testing was required for this device.

Integration and System Performance Testing

The subject device uses the same firmware as the predicate device (K231289). Therefore, no additional Integration and System Performance Testing was required for this device.

Cybersecurity Assessment and Testing

The subject device uses the same firmware as the predicate device (K231289). Therefore, no additional cybersecurity assessment and Testing were required for this device.

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. The subject device has the same usage method and similar design as the predicate device (K231289), differing primarily in the

size of the battery side. The change in battery size does not affect the critical tasks of the predicate device and does not introduce new critical tasks.

Clinical Study

Clinical study was not required for demonstrating safety, effectiveness of the subject device and significant equivalence to the predicate device.

10. Conclusion

The subject device S-Patch ExL ECG Patch System is substantially equivalent in indications for use, functions, and performance to the predicate device. The minor difference in battery type between the subject and predicate device was adequately evaluated and did not raise any new or different questions regarding the safety and effectiveness of the device 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 ExL ECG Patch System is substantially equivalent to the predicate device.