



September 25, 2026

Wellysis Corp.
Young Juhn
CEO
8f, 425 Teheran-Ro Gangnam--Gu
Seoul, Republic Of Korea

Re: K254255
Trade/Device Name: S-Patch CardioAI
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: August 24, 2026
Received: August 25, 2026

Dear Young Juhn:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

KIMBERLY N. CROWLEY -
S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254255

?

Please provide the device trade name(s).

?

S-Patch CardioAI

Please provide your Indications for Use below.

?

S-Patch CardioAI is a software application intended for the assessment of cardiac arrhythmias using ambulatory ECG data in adults. It is intended for use by a healthcare solution integrator to build web, mobile, or other types of applications that allow qualified healthcare professionals to review and confirm the analytic results. The product supports downloading and analyzing data recorded in compatible formats from FDA-cleared S-Patch Ex and S-Patch ExL devices when assessment of the rhythm is necessary. S-Patch CardioAI can be electronically interfaced to perform analysis on data transferred from other computer-based ECG systems, such as an ECG management system. S-Patch CardioAI is not intended for use in life-supporting or life-sustaining systems or ECG Alarm devices. The interpretation results generated by S-Patch CardioAI are not intended to be the sole means of diagnosis. Interpretation of the device output must be made by the clinician; the results are offered to physicians and clinicians on an advisory basis only, to be used in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

CAUTION - Federal (U.S.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

510(k) Summary

Date Prepared:	September 24, 2026
Submitter/Applicant:	Wellysis Corp. 8F, 425, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea
Official Contact:	Dennis Ahn, Quality Assurance Manager
Primary Contact Person:	Dennis Ahn Quality Assurance Manager, Wellysis USA Email: dennis.ahn@wellysis.com Phone: (217) 298-6850
Secondary Contact Person:	Robert Kazmierski Regulatory Consultant, MCRA. Email: rkazmierski@mcra.com Phone: (443) 831-5064
Proprietary or Trade Name:	S-Patch CardioAI
Common/Usual Name:	Electrocardiograph
Classification Name:	21CFR 870.1425 DQK and DPS Class II
Predicate Device:	DeepRhythmAI, K210822

Device Description:

S-Patch CardioAI is proprietary Software as a Medical Device (SaMD) intended for the automated processing and analysis of single-lead electrocardiogram (ECG) data obtained from S-Patch Ex and S-Patch ExL devices. Operating as a backend analysis engine, it uses a scalable Application Programming Interface (API) to integrate with third-party medical systems that offer visualization and user interface. The product is designed exclusively to provide supportive analytical information to qualified healthcare professionals for review.

The core of S-Patch CardioAI is the deep-learning algorithm that combines rule-based logic with advanced AI/ML technology. This hybrid architecture analyzes the temporal context of ECG waveforms to accurately detect cardiac beats, classify arrhythmias, and assess signal quality.

S-Patch CardioAI can be used to analyze both continuous ECG as well as event recordings. Upon processing, it can generate cardiac classifications and metrics including:

- QRS
- Heart rate determination
- Heart rate variability measurements

- RR Interval measurements
- Non-paced arrhythmias
- Non-paced ventricular arrhythmia calls
- Ventricular ectopic beats
- Supraventricular ectopic beats
- Unreadable (signal-quality) interval determination

S-Patch CardioAI can be deployed as a flexible solution capable of residing within compatible secure computing environments.

Indications for Use:

S-Patch CardioAI is a software application intended for the assessment of cardiac arrhythmias using ambulatory ECG data in adults.

It is intended for use by a healthcare solution integrator to build web, mobile, or other types of applications that allow qualified healthcare professionals to review and confirm the analytic results.

The product supports downloading and analyzing data recorded in compatible formats from FDA-cleared S-Patch Ex and S-Patch ExL devices when assessment of the rhythm is necessary.

S-Patch CardioAI can be electronically interfaced to perform analysis on data transferred from other computer-based ECG systems, such as an ECG management system.

S-Patch CardioAI is not intended for use in life-supporting or life-sustaining systems or ECG Alarm devices. The interpretation results generated by S-Patch CardioAI are not intended to be the sole means of diagnosis. Interpretation of the device output must be made by the clinician; the results are offered to physicians and clinicians on an advisory basis only, to be used in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

CAUTION - Federal (U.S.) law restricts this device to sale, distribution, and use by or on the order of a licensed healthcare practitioner.

Environments of use:

S-Patch CardioAI is intended for use within secure, controlled computing environments, and its analysis functions are accessed exclusively through its Application Programming Interface (API) by third-party software systems. S-Patch CardioAI supports clinical workflows in home, clinic, and hospital settings through integrated applications that present the analysis results to qualified healthcare professionals. A separate administrative web interface (the Admin Dashboard) is provided for administrators to manage tenants and accounts; it presents no clinical information, supports no clinical task, and is not used for ECG analysis.

Table 3.1. outlines the proposed device vs. the predicate.

As part of the comparison, the following shall be presented & discussed:

- Indications for Use

- Technology and Principle of Operation
- Performance and Specifications

Table 3.1 – Comparison – Subject vs. Predicate

	Predicate DeepRhythmAI	Subject device S-Patch CardioAI	Comments
K#	K210822	K254255	N/A
Product Code	DQK and DPS	DQK and DPS	Same
Classification	Class II	Class II	Same
Regulation Number(s)	21 CFR §870.1425 21 CFR §870.2340	21 CFR §870.1425 21 CFR §870.2340	Same
Classification name	Programmable Diagnostic Computer, Electrocardiograph	Programmable Diagnostic Computer, Electrocardiograph	Same
Indications for Use	DeepRhythmAI is a cloud-based software for the assessment of cardiac arrhythmias using two lead ECG data in adult patients. It is intended for use by a healthcare solution integrator to build web, mobile or another types of applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry or other similar devices when the assessment of the rhythm is necessary. The product can be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system.	S-Patch CardioAI is a software application intended for the assessment of cardiac arrhythmias using ambulatory ECG data in adults. It is intended for use by a healthcare solution integrator to build web, mobile, or other types of applications that allow qualified healthcare professionals to review and confirm the analytic results. The product supports downloading and analyzing data recorded in compatible formats from FDA-cleared S-Patch Ex and S-Patch ExL devices when assessment of the rhythm is necessary. S-Patch CardioAI can be electronically interfaced to perform analysis on data transferred from other computer-based ECG systems, such as an ECG management system. S-Patch CardioAI is not intended for use in life-supporting or life-sustaining	Similar - compatible devices have been evaluated with performance testing

	Predicate DeepRhythmAI	Subject device S-Patch CardioAI	Comments
	DeepRhythmAI can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. DeepRhythmAI is not for use in life-supporting or sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.	systems or ECG Alarm devices. The interpretation results generated by S-Patch CardioAI are not intended to be the sole means of diagnosis. Interpretation of the device output must be made by the clinician; the results are offered to physicians and clinicians on an advisory basis only, to be used in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information. CAUTION - Federal (U.S.) law restricts this device to sale, distribution, and use by or on the order of a licensed healthcare practitioner.	
Components	Software only: 1) A web API 2) An automated proprietary algorithm.	Software only: 1) A web API 2) An automated proprietary algorithm.	Same
Interface	Web application programming interface (API)	Web application programming interface (API)	Same
Part responsible for ECG signal analysis	The automated proprietary deep-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information for review.	The automated proprietary deep-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information for review.	Same
Number of leads for a received ECG signal	Two-lead ECG	Single-lead ECG	Similar – compatible devices have been evaluated with performance testing
Display or Graphical User Interface (GUI)	No primary display or GUI	No primary display or GUI	Same

Analysis Output Comparison

Device functionality	S-Patch CardioAI	DeepRhythmAI (K210822) ¹
QRS	YES	YES
Heart rate determination	YES	YES
R-R interval measurement	YES	YES
Heart rate variability measurements	YES	Not stated in the cleared 510(k) Summary
Non-paced arrhythmia	YES	YES
Non-paced ventricular arrhythmia calls	YES	YES
Atrial fibrillation detection	YES	YES
Ventricular ectopic beats	YES	YES
Supraventricular ectopic beats	YES	YES
Unreadable (signal-quality) interval determination	YES	Not stated in the cleared 510(k) Summary

Predicate entries are taken from the cleared K210822 510(k) Summary. "Not stated" indicates that the cleared summary does not describe the item; it is not a statement about the predicate's capability.

The two subject-device outputs not described in the cleared predicate summary — heart-rate-variability indices and the Unreadable (signal-quality) interval determination — are adjunct outputs that were independently validated in the clinical performance testing. They do not alter the intended use or raise no new question of safety or effectiveness compared to the predicate.

Substantial Equivalence Discussion

S-Patch CardioAI has the same general intended use and similar indications as the predicate device. The subject device's indications for use specify a patient population of adults, consistent with the intended-use population evaluated in performance testing to align with the predicate device's intended-use population. Accordingly, the subject and predicate devices share the same intended-use age range, and this does not constitute a new or different intended use, nor does it raise new questions of safety or effectiveness. The subject device shares the same technological characteristics as the predicate, including compliance with ANSI/AAMI/IEC 60601-2-47, AAMI/ANSI/EC57, and ANSI/AAMI/IEC 62304. A difference in technological characteristics exists in that the subject device uses a single-lead ECG from previously cleared S-Patch devices, as opposed to the predicate's compatibility with two-lead ECGs. This single-lead configuration was validated in the clinical performance testing, and this difference in technological characteristics therefore does not raise new questions of safety or effectiveness.

A further difference exists in the output sets of the two devices: the subject device's core measurement outputs (QRS/heart-rate determination, RR interval measurements, non-paced arrhythmias, non-paced ventricular arrhythmia calls, atrial fibrillation detection, ventricular ectopic beats, and supraventricular ectopic beats) are the same as the predicate's, and it additionally provides heart-rate-variability metrics and the Unreadable (signal-quality) interval determination. These differences do not raise new questions of safety or effectiveness and have been appropriately evaluated to demonstrate the device remains as safe and effective as the predicate device through non-clinical testing according to

AAMI/ANSI/EC57:2012 and clinical performance testing.

Non-clinical Performance Testing

Non-clinical performance testing was conducted in accordance with ANSI/AAMI EC57:2012/(R)2020 using the standard annotated arrhythmia databases referenced by that standard. Beat detection, beat classification, and ectopic run detection were evaluated.

Clinical Performance Testing

Clinical performance was evaluated retrospectively using 24-hour S-Patch ECG recordings from 496 unique adult patients across five clinical sites, including three U.S. sites. The validation cohort was independent from model training, tuning, and threshold selection.

Independent cardiologist-adjudicated annotations were used as the clinical reference for beat detection and classification and atrial fibrillation (AF), and an independently adjudicated readability reference was used for the Unreadable output. The table below summarizes the performance of these directly reference-validated outputs. The clinical reference annotations were established through independent cardiologist review and adjudication.

Output	Clinical Performance (Se/+P)
QRS Detection	99.9% / 99.4%
Normal Beat (N) Classification	100.0% / 99.6%
SVEB (S) Classification	94.6% / 90.2%
VEB (V) Classification	97.3% / 92.5%
Atrial Fibrillation (episode)	95.4% / 94.7%
Unreadable	90.7% / 94.6%

All pre-specified acceptance criteria established for these directly validated outputs were met. Other device outputs were evaluated using validation methods appropriate to each output.

Subgroup analyses across demographic, site/region, rhythm-burden, and recorder-model strata did not identify evident performance degradation in estimable subgroups; low-count strata were descriptively.

Conclusion

In conclusion, S-Patch CardioAI has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness. Differences between the subject device and the predicate have been tested to ensure that the device meets its intended use. Therefore, S-Patch CardioAI is substantially equivalent to the predicate device.