June 18, 2026

Zywie, Inc
Latha Ganeshan
CEO
12000 Findley Road, St. 360
Johns Creek, Georgia 30097

Re: K252839
Trade/Device Name: ZywieZ3 Sensor & Adhesive
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: May 15, 2026
Received: May 18, 2026

Dear Latha Ganeshan:

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,

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

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.	K252839

Please provide the device trade name(s).

ZywieZ3 Sensor & Adhesive (ZywieZ3 ECG Monitor)

Please provide your Indications for Use below.

The ZywieZ3 Sensor is a wireless device intended for use by healthcare professionals to record and display physiological data for patients requiring outpatient cardiac monitoring, both at home and in healthcare settings. When used with the ZywieZ3 Adhesive, the device captures electrocardiogram (ECG) data and wirelessly transmits it to a separate device- such as a mobile phone- for storage, display, and transmission. This is an ambulatory, continuous recording system designed for general patient care. It is not intended for critical care patients and does not replace standard clinical monitoring practices. Instead, it provides physiological data recordings for later review by healthcare professionals. The device is not intended to provide real-time interpretative or diagnostic information.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) Summary
As required by 21 CFR 807.92(c)

Device Name	ZywieZ3 Sensor & Adhesive
Submitters name /contact details	Latha Ganeshan, *President & CEO*, Zywie, Inc. 12000 Findley Road, Suite 360, Johns Creek, GA 30097 USA Mail: latha.ganeshan@zywie.net Web: www.zywie.healthcare Telephone Number: +1-877.858.7200
Manufactured by	Syrma Johari MedTech Ltd. (Formerly known as Johari Digital Healthcare Limited) G-582-584, E.P.I.P., Boranada, Jodhpur,342012, India
Summary Preparation Date	June 17, 2026
Device Trade Name	ZywieZ3 Sensor & Adhesive
Classification Name	Electrocardiograph, Ambulatory (Without Analysis)
Classification Regulation	21 CFR 870.2800, Class II
Classification Product Code	MWJ

Legally marketed Predicate Device

Predicate Device

Device Name	Q Patch
510(K) No	K210758
Regulation No	21 CFR 870.2800
Product Classification Code	MWJ
Company Name	Medicalgorithmics S.A.
Establishment Registration number	3007770164
Owner/ Operator Number	Medicalgorithmics S.A. / 10029709

Device Description

The ZywieZ3 Sensor is a three-channel, rechargeable, reusable, ambulatory medical-grade device intended for continuous recording, storage, and transmission of physiological data such as electrocardiogram (ECG) signals. The device is worn on the body using the disposable ZywieZ3 Adhesive, which ensures secure skin contact through its hydrogel that senses electrical signals and conducts them to the sensor. Once fully charged, the sensor can be used continuously for up to 10 days.

The device is intended for general care in healthcare facilities or home environments, is not intended for use with critical care patients, and does not replace current standards of care. The device is intended for outpatient ECG monitoring and does not provide real-time interpretive or diagnostic information. It is not intended to be compatible with and should not be used with automated/semi-automated ECG analysis software.

It pairs with a mobile device to transmit physiological data, allowing for near real-time viewing by authorized users. Data can be viewed directly on the paired device or through an application that securely receives encrypted transmissions for review by healthcare professionals. The ZywieZ3 Sensor includes operational alarms for lead-on/lead-off status and battery status but does not generate alarms based on the physiological data itself. Firmware updates can be delivered over-the-air (OTA) to maintain optimal functionality.

The ZywieZ3 sensor comes with the ZywieZ3 Software Development Kit (SDK), which enables secure integration with third-party systems for the purpose of data transfer, interoperability, and review. The SDK facilitates controlled access to recorded ECG data and related device information, and it operates within the manufacturer-defined system architecture. The SDK does not independently perform diagnosis, clinical interpretation, or clinical decision-making, and its use does not modify the intended use of the device.

To support integration with compatible mobile applications, the system must utilize the ZywieZ3 SDK. Zywie will not provide Android phones to third-party developers; it will be the responsibility of the third-party developers to procure their own phones and create an end-user application in accordance with the requirements listed in the ZywieZ3 SDK documentation. While Zywie does not control third-party applications, the SDK includes built-in security features and requirements to support secure implementation and reduce cybersecurity risks. Third-party developers are responsible for ensuring that their applications follow all cybersecurity best practices to prevent unauthorized access to patient data or manipulation of device functionality.

The authorized third-party developers shall ensure that their mobile application either (a) strictly adheres to the Zywie's instructional video language, content, and process flow, or (b) independently conducts and documents usability validation demonstrating equivalence to the Zywie's instructional video. Any deviation from content, or process flow remains the responsibility of the third-party and shall be managed in accordance with applicable quality and regulatory requirements.

The ZywieZ3 sensor is designed for multiple-patient use and is intended to be cleaned only using disinfectant wipes, as described in the Instructions for Use. The sensor is not intended to be immersed, soaked, sprayed with liquid disinfectants, or subjected to sterilization processes. Improper cleaning methods may damage the device and affect performance. The ZywieZ3 sensor can be reused provided that it is well-maintained and does not exhibit signs of

deterioration. Device diagnostic and basic operational testing, along with routine visual inspections, are recommended before each use to identify any visible issues, such as corrosion of snaps, discoloration, pitting, or damaged seals. If any of these issues are observed, the device should be retired and replaced to ensure patient safety and the accurate functioning of the device.

The ZywieZ3 Sensor is non-serviceable and non-repairable while in use. Faulty units should be returned to the Zywie support team. The sensor and its accessories have a service life of five years, while the ZywieZ3 Adhesive has a shelf life of one year from the manufacturing date, clearly labeled in the YYYY-MM-DD format on the adhesive pouch. The ZywieZ3 Sensor has been tested and demonstrated to be safe during defibrillation.

Healthcare professionals reviewing the ECG tracings should note that there may be reduced amplitudes and missing or inverted ECG morphologies due to device characteristics.

Accessories Description

Name of accessories	Quantity
ZywieZ3 Sensor	1
Disposable Adhesive Pouch with ZywieZ3 Adhesive	1
Docking station	1
USB charging cable	1
Adapter plug	1
Alcohol wipes	Based on ECG study duration
Adhesive removal pads	Based on ECG study duration
Resealable bag	1
Patient guide	1

Indications for Use

The ZywieZ3 Sensor is a wireless device intended for use by healthcare professionals to record and display physiological data for patients requiring outpatient cardiac monitoring, both at home and in healthcare settings. When used with the ZywieZ3 Adhesive, the device captures electrocardiogram (ECG) data and wirelessly transmits it to a separate device- such as a mobile phone- for storage, display, and transmission.

This is an ambulatory, continuous recording system designed for general patient care. It is **not intended** for critical care patients and does not replace standard clinical monitoring practices. Instead, it provides physiological data recordings for later review by healthcare professionals. The device is not intended to provide real-time interpretative or diagnostic information.

Comparison of Technological Characteristics

The device's substantial equivalence was demonstrated by performance data and a comparison of technical characteristics between the new device and the predicate device. A comparison given below identifies all the changes between the subject and the predicate device:

Features	Predicate Device	Subject Device	Comparison
Device Name	Q Patch	ZywieZ3 Sensor & Adhesive	-
OTC/Rx	Rx	Rx	Identical
Proprietary Name	Medicalgorithmics S.A.	Zywie, Inc.	-
510(k) Number	K210758	K252839	-
Regulation Number	21 CFR 870.2800	21 CFR 870.2800	Identical
Product Code	MWJ	MWJ	Identical
Indication for Use	The Medicalgorithmics' Q Patch is intended to be used by patients who have a demonstrated need for extended cardiac monitoring and patients with symptoms that may be due to cardiac arrhythmias such as, dizziness, lightheadedness, shortness of breath, palpitations, dyspnea (shortness of breath), anxiety, syncope of unknown etiology in which arrhythmias are suspected or need to be excluded. It is indicated for use on adult patients. The sensor records single ECG channel for up to 15 days and can be used on patients with implanted pacemakers but is not intended to record pacemaker activity.	The ZywieZ3 Sensor is a wireless device intended for use by healthcare professionals to record and display physiological data for patients requiring outpatient cardiac monitoring, both at-home and in healthcare settings. When used with the ZywieZ3 Adhesive, the device captures electrocardiogram (ECG) data and wirelessly transmits it to a separate device- such as a mobile phone- for storage, display, and transmission. This is an ambulatory, continuous recording system designed for general patient care. It is not intended for critical care patients and does not replace standard clinical monitoring practices. Instead, it provides physiological data recordings for later review by healthcare professionals. The device is not intended to provide real-time interpretative or	Similar

Features	Predicate Device	Subject Device	Comparison
		diagnostic information.	
Intended Use	Wireless recording and display of physiological data	Wireless recording and display of physiological data	Identical
Intended Users	Healthcare Professionals	Healthcare Professionals	Identical
Intended Population	General care for patients greater than 21 years of age	General care for patients greater than 21 years of age	Identical
Intended Use Environment	Healthcare facilities, Home, Office, Car, Outside under proper clothing.	Healthcare facilities, Home, Office, Outdoors	Similar
Device Placement on Human Body	Placed on the sternum (in the middle of the chest)	Left upper chest area	Equivalent
Reuse	Q Patch Sensor: Reusable	ZywieZ3 Sensor: Reusable	Identical
	Adhesive: Disposable	ZywieZ3 Adhesive: Disposable	Identical
Duration of Continuous Use	Up to 15 days powered from single disposable, non-rechargeable battery	10 days of continuous recording. Charge the device again and reuse it.	Similar
Sterility	Non-Sterile	Non-Sterile	Identical
Battery	Single-use, non-rechargeable battery	Rechargeable battery	Equivalent
Weight	25 gm	27 gm	Equivalent
Wireless Transmission	Near Field Communication (NFC)	Bluetooth Low Energy (BLE)	Similar
Operating Temperature	10 – 45 degrees C	10 – 45 degrees C	Identical
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Identical
Electromagnetic Compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Identical
Electrocardiogram (ECG) Display	Yes	Yes	Identical
Performance	Conformed to IEC 60601-2-47	Conformed to IEC 60601-2-47	Identical
Biocompatibility	Conformed to ISO 10993-1	Conformed to ISO 10993-1, ISO 10993-5 and ISO 10993-10	Identical
Principle of Operation	Continuous physiological data recorder	Continuous physiological data recorder	Identical
Components of Device	One-channel ECG device with electrodes	Three-channel ECG device with electrodes	Equivalent

In comparison to the predicate device, there is no change or difference in the indications for

use, fundamental scientific principles, performance specifications, or operation of the device. The fundamental scientific technology is not changed in the new device, and the differences are solely considered for ease of use to the user.

Performance Data

The following performance data support the determination of substantial equivalence.

Non-clinical Bench Testing

Nonclinical testing included bench performance testing, software verification and validation, and cybersecurity risk management activities. Software testing was conducted in accordance with the device's software level of concern and applicable FDA guidance. The ZywieZ3 sensor and adhesive was considered an Enhanced Documentation Level. In accordance with the FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – February 3, 2026*, cybersecurity testing was conducted to identify and mitigate potential risks, supporting data integrity and device functionality.

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the predicate device. The ZywieZ3 Sensor device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared device. No new safety or performance issues were raised during testing.

S/N	Standards	Title of Standard	FDA Recognition Number
1.	IEC 62366-1:2015/Amd 1:2020	Medical devices — Part 1: Application of usability engineering to medical devices	5-129
2.	ISO 10993-2:2022	Biological evaluation of medical devices – Part 2: Animal welfare requirements	2-300
3.	ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation	2-291
4.	ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization	2-296
5.	ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	2-289
6.	ANSI/AAMI/ISO 10993-5	Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity	2-245

S/N	Standards	Title of Standard	FDA Recognition Number
7.	ISO 14971:2019	Application of risk management to medical devices	5-125
8.	ASTM F 1980-2021	Standard Guide for Accelerated Ageing of Sterile Barrier Systems for Medical Devices	14-575
9.	ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
10.	IEC 60601-1 Edition 3.2 2020-08 Consolidated version	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-49
11.	IEC 60601-2-47:2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	3-155
12.	IEC 60601-1-2:2014+A1:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility – Requirements and tests	19-36
13.	IEC 60601-1-11:2015	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	19-38

S/N	Standards	Title of Standard	FDA Recognition Number
14.	IEC TR 60601-4-2:2016	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical system	19-19
15.	AIM 7351731 Rev. 3.00 (2021-06-04)	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers	19-45

Clinical Testing- ZywieZ3 Device Clinical Performance

The clinical evaluation assessed the performance and robustness of the ZywieZ3 Sensor and Adhesive under conditions representative of intended use. The study compared ECG signal quality from the ZywieZ3 device to that of a conventional 3-lead ECG reference system using wet Ag-AgCl electrodes during simultaneous recordings. Additional testing evaluated sustained ECG signal quality over an extended simulated wear period, along with adhesive integrity, skin compatibility, and the potential for material degradation or skin reactions. The evaluation further examined the impact of variability in electrode placement to confirm that acceptable placement ranges did not result in clinically non-relevant ECG data.

A total of 45 adult subjects participated in the clinical evaluation. Participants ranged in age from 21 to 80 years and included both male and female subjects. The study population represented a wide range of BMI categories, including healthy weight, overweight, and obese individuals, as well as diverse educational backgrounds and racial groups. Subjects with self-reported limited hand or arm dexterity were also included, supporting assessment of device usability across a representative intended-use population.

The clinical data demonstrate that the ZywieZ3 Sensor and ZywieZ3 Adhesive provide clinically interpretable ECG recordings comparable to a conventional ECG system, maintain stable signal quality throughout the intended duration of use, and are not adversely affected by minor electrode placement variability. Adhesion, skin compatibility, and usability findings support the safety and effectiveness of the device for its intended use compared to the predicate.

Usability Engineering

A total of 25 subjects with a median range of 40 years (22-74 years) participated in the summative usability testing of the ZywieZ3 Sensor and Adhesive, representing a range of demographic characteristics, including varied body mass indices (BMIs), both sexes, and education levels.

Human factors and usability were assessed through observation of user performance on

sponsor-identified critical tasks, knowledge-based assessments, and collection of subjective user feedback, consistent with FDA's recommendations and requirements related to human factors and usability engineering to medical devices. The human factors evaluation demonstrated successful completion of all identified critical tasks and acceptable usability during extended wear, with no unmitigated use-related hazards identified.

Conclusion

The ZywieZ3 Sensor & Adhesive device is substantially equivalent to the predicate device (K210758) and is indicated for the same clinical application as the predicate device. There are a few minor technological/design differences that do not raise new issues of safety or effectiveness. The predicate device has the same intended use, indications for use, intended users, intended population, and regulation number. Based on the test results, compliance with FDA-recognized standards, and the analysis provided in this notice, the ZywieZ3 Sensor & Adhesive is shown to be substantially equivalent to the predicate device.