July 10, 2025

ZBeats Inc.
% Christopher Ford
Regulatory Affairs Consultant
Zaliance Medical Solutions
5153 West Wooley Rd
Oxnard, California 93035

Re: K243252
Trade/Device Name: ZBPro Diagnostic
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: June 13, 2025
Received: June 13, 2025

Dear Christopher Ford:

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.

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)*
K243252

Device Name
ZBPro Diagnostic

Indications for Use *(Describe)*
ZBPro Diagnostic is a cloud-based medical device intended for use by qualified healthcare professionals in the detection and analysis of common cardiac arrhythmias in Holter ECG data in the adult, non-paced population.

The product supports downloading and analyzing Lead II, CM5 (Ch 1), or Modified-MLII (Ch 2+) on retrospective 3-lead and 5-lead 24/48-hour Holter ECG recordings collected using standard Ag/AgCl wet electrodes in adult, non-paced patients. ZBPro is not intended for use with multi-lead analysis, wearable patches, or pediatric/paced recordings.

ZBPro Diagnostic can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system.

ZBPro Diagnostic provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, R-R interval measurement, heart rate measurement, and rhythm analysis.

ZBPro Diagnostic is not for use in life-supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

ZBPro Diagnostic 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.

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.

510(K) Summary

5.1 Applicant/Submitter

Company Name	: ZBeats, Inc
Street Address	: 25 Health Sciences Drive
City	: Stony Brook NY
State	: NY
Zip Code	: 11790
Phone Number	: (631) 220-2463

5.2 Contact Person

Full Name	: Bin Fang
Phone	: (631) 220-2463

5.3 Correspondent Information

Full Name	: Christopher Ford
Phone	: (916) 612-9954

5.4 Date of Preparation

Date of Preparation	: 07/10/2025

5.5 Device Information

Device Name	ZBPro Diagnostic
Model Number	

Common Name	ECG Analysis System
Regulation	21 CFR 870.2340, 21 CFR 870.1425
Product Code	DPS;DQK
Reviewing Panel/Branch	Cardiovascular
Submission Number	K243252

5.6 Predicate Device(s)

Table - 5.1 Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer	Product Code
Primary	K212112	Cardiologs Holter Platform	Cardiologs Technologies	DPS, DQK

5.7 Indications for Use

ZBPro Diagnostic is a cloud-based medical device intended for use by qualified healthcare professionals in the detection and analysis of common cardiac arrhythmias in Holter ECG data in the adult, non-paced population.

The product supports downloading and analyzing Lead II, CM5 (Ch 1), or Modified-MLII (Ch 2+) on retrospective 3-lead and 5-lead 24/48-hour Holter ECG recordings collected using standard Ag/AgCl wet electrodes in adult, non-paced patients. ZBPro is not intended for use with multi-lead analysis, wearable patches, or pediatric/paced recordings.

ZBPro Diagnostic can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system.

ZBPro Diagnostic provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, R-R interval measurement, heart rate measurement, and rhythm analysis.

ZBPro Diagnostic is not for use in life-supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

ZBPro Diagnostic 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.

5.8 Device Description

ZBPro is cloud-based Software as a Medical Device which aids healthcare professionals in interpreting ambulatory ECG recordings. The software comprises a secure web interface and a backend server hosted on Amazon Web Server (AWS). Authenticated users upload compatible 24-48 hour Holter ECG recordings via a web browser through an Application Programming Interface (API). ZBPro’s proprietary ECG interpretation algorithm analyzes and annotates ECGs to provide supportive information for ECG and arrhythmia analysis.

ZBPro provides beat-by-beat ECG signal processing and analysis, QRS detection, Ventricular Ectopic Beat detection, R-R interval measurement, heart rate and Heart Rate Variability measurement, and rhythm analysis.

ZBPro consists of:

1. A web interface which provides tools to upload data, measure, analyze and review numerous ECGs and patient diary logs, make manual annotation and generate ECG reports.
2. An automated proprietary ECG interpretation algorithm which measures and analyzes ECGs to provide adjunct information for ECG diagnosis.

The backend application is established in Amazon Web Services (AWS) and accessed through an Internet connection and a web browser to perform ECG analysis and generate reports.

5.9 Intended Use/Indications for Use Comparison

ZBPro Diagnostic (K243252) and the Cardiologs Holter Platform (K212112) are both cloud-based ECG analysis platforms intended for retrospective review of ambulatory electrocardiogram (ECG) recordings to assist qualified healthcare professionals in detecting and analyzing cardiac arrhythmias. Both systems support integration with external ECG acquisition devices and provide core analytical functions including QRS detection, rhythm classification, ectopic beat detection, and heart rate trend analysis.

The technological differences between ZBPro Diagnostic and its predicate are limited to algorithmic design and scope of use. These differences are mitigated through validated performance, labeling restrictions, and risk controls. ZBPro Diagnostic is substantially equivalent to the Cardiologs Holter Platform and raises no new questions of safety or effectiveness as compared to the predicate.

Both devices are intended for use by qualified healthcare professionals to detect and analyze common cardiac arrhythmias using retrospective ambulatory ECG data. The primary indication (arrhythmia assessment in Holter ECG recordings in adult patients) is identical in both devices, and both utilize well-established principles of signal processing, QRS detection, rhythm classification, and clinical data presentation.

The primary differences relate to patient population and recording source compatibility. ZBPro Diagnostic is limited to the adult, non-paced population, whereas Cardiologs includes pediatric and paced patient populations and accepts data from additional sources (e.g., event recorders, 12-lead ambulatory ECG). These differences reflect scope of validation rather than underlying technological capabilities and do not introduce new questions of safety or effectiveness. ZBPro's intended use is clearly delineated in its labeling and supported by clinical validation.

Both devices support electronic interfacing with other ECG systems and offer nearly identical functional capabilities, including ECG signal processing, ventricular ectopy detection, interval and heart rate analysis, and comprehensive rhythm interpretation. Neither system is intended for use in life-sustaining applications or real-time monitoring, and both clearly state that their results are to be used in conjunction with clinician oversight, not as a standalone diagnostic decision-maker.

While Cardiologs has broader input compatibility and population coverage, ZBPro maintains equivalence in intended use and analytical functionality. The observed differences are managed through labeling and intended use limitations. Therefore, these distinctions do not impact the substantial equivalence of the two systems in their shared core function to provide automated ECG interpretation support for adult Holter monitoring data.

5.10 Comparison of Technological Characteristics with Predicate

The subject device has the same intended use and substantially equivalent technological characteristics that do not raise questions of safety or effectiveness as the predicate. Table - 5.2 Feature Comparison: ZBPro Diagnostic to the predicate device illustrates a comparison of detection features between ZBPro Diagnostic and the cited predicate.

Table - 5.2 Feature Comparison: ZBPro Diagnostic to the predicate device

Feature	ZBPro Diagnostic	Cardiologs Holter Platform
Heart rate determination for non-paced adult	Yes	Yes
QRS Detection	Yes	Yes
Non-paced arrhythmia interpretation for adult patients	Yes	Yes
Non-paced ventricular arrhythmia calls	Yes	Yes

R-R Intervals measurements	Yes	Yes
Ventricular ectopic beat detection	Yes	Yes
Patient Population	Adult	Adult & Pediatric

Table - 5.3 Comparison of technological characteristics: ZBPro Diagnostic to the predicate device provides a comparison of the technological characteristics of the ZBPro Diagnostic with the cited predicate.

Table - 5.3 Comparison of technological characteristics: ZBPro Diagnostic to the predicate device

	ZBPro Diagnostic (this submission)	Cardiologs Holter Platform	Comparison to predicate device
Device Trade Name	ZBPro Diagnostic	CardioLogs ECG Analysis Platform	N/A
Manufacturer	ZBeats, Inc.	CardioLogs Technologies	N/A
510(K) No.	(this submission)	K212112	N/A
Regulation Number	21 CFR 870.2340 21 CFR 870.1425	21 CFR 870.2340 21 CFR 870.1425	Same
Product Code	DQK, DPS	DQK, DPS	Same
Class	2	2	Same
Device Class/Name	Electrocardiograph	Electrocardiograph	Same
Indications for Use	ZBPro Diagnostic is a cloud-based medical device intended for use by qualified healthcare professionals in the detection and analysis of common cardiac arrhythmias in Holter ECG data in the adult, non-paced population. The product supports downloading and analyzing Lead II, CM5 (Ch 1), or Modified-MLII (Ch 2+) on retrospective 3-lead and 5-lead 24/48-hour Holter ECG recordings collected using standard Ag/AgCl wet electrodes in adult, non-paced patients. ZBPro is not intended for use with multi-lead analysis, wearable patches, or pediatric/paced recordings. ZBPro Diagnostic can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. ZBPro Diagnostic provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, R-R interval measurement, heart rate measurement, and rhythm analysis. ZBPro Diagnostic is not for use in life-supporting or sustaining	Cardiologs Holter Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population. The product supports downloading and analyzing data recorded in compatible formats from any device used for arrhythmia diagnostics such as Holter, event recorder, 12-lead ambulatory ECG devices, or similar devices when assessment of the rhythm is necessary. The Cardiologs Holter Platform can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. Cardiologs provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. Cardiologs is not for use in life-supporting systems or ECG monitor and Alarm devices. The product can be integrated into computerized ECG monitoring	Both are cloud-based medical devices intended for use by qualified healthcare professionals in the detection and analysis of common cardiac arrhythmias in Holter ECG data in the adult, non-paced population. However, Cardiologs is also intended for use on pediatric patients and paced patients. This increased compatibility does not introduce new questions of safety or efficacy as compared to the predicate as both systems use well-established principles of ECG signal detection and analysis and are validated for their intended uses. Both products support downloading and analyzing equivalent vectors on retrospective 3-lead and 5-lead 24/48-hour Holter ECG recordings taken with standard Ag/AgCl wet electrodes, however Cardiologs supports event recorders, 12-lead ambulatory ECG devices, and similar recording devices. This increased compatibility does not introduce new questions of safety or efficacy compared to the predicate as both systems use well-established principles of ECG signal detection and analysis and are validated for their intended uses.

	ZBPro Diagnostic (this submission)	Cardiologs Holter Platform	Comparison to predicate device
	systems or ECG monitor and Alarm devices. The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. ZBPro Diagnostic 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.	devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. Cardiologs interpretation results are not intended to be the sole means of diagnosis and are offered to physicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient history, and other diagnostic information.	
Fundamental scientific technology	ZBPro consists of: A web interface which provides tools to upload data, measure, analyze and review numerous ECGs and patient diary logs, make manual annotation and generate ECG reports. An automated proprietary ECG interpretation algorithm which measures and analyzes ECGs to provide adjunct information for ECG diagnosis. The backend application is established in Amazon Web Services (AWS) and accessed through an Internet connection and a web browser to perform ECG analysis and generate reports.	The Cardiologs Holter Platform consists of: An interface which provides tools to measure, analyze and review numerous ECGs coded in java language under the Angular and D3.js frameworks; An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide supportive information for ECG diagnosis, written in Python language. This application can be accessed through an Internet connection and a web browser, or is directly connected to the Cardiologs' Application Programming Interface (API).	ZBPro Diagnostic does not present any major technological differences compared to the predicate device. Substantially equivalent: Both devices provide a web interface which provides tools to upload, analyze, review ECG data. Both consist of a proprietary ECG interpretation support algorithm and are not intended to be the sole means of diagnosis. The interpretations are offered to physicians on an advisory or assistive basis. While the two platforms differ in input generalization and architectural approach, these differences do not alter the shared fundamental technology purpose of ECG rhythm analysis for Holter monitoring. ZBPro Diagnostic achieves equivalent clinical functionality within its labeled scope and is therefore substantially equivalent in its technological characteristics to the predicate device. Both are accessed through an internet connection and a web browser, but the predicate device can also be accessed through a direct connection to the API. This connection difference should not have any effect on intended use or performance and does not introduce new issues of safety or effectiveness as compared to the predicate.

ZBPro Diagnostic and the Cardiologs Holter Platform are both cloud-based ECG analysis systems designed to receive, process, and support clinician review of retrospective ambulatory ECG recordings. Both platforms provide secure, browser-accessible environments, RESTful API integration, and clinical tools for ECG visualization, annotation, and cardiologist confirmation.

The core technologies used by each platform are similar in functional intent but differ in algorithmic framework implementation. ZBPro Diagnostic processes standard-format Holter ECG files (MIT-BIH, EDF, ISHNE) acquired with validated lead configurations (Lead II, CM5 (Ch 1), or Modified-MLII (Ch 2+)).

From a technological architecture perspective, both systems:

a. Operate via secure, cloud-hosted infrastructure;
b. Offer browser-based access for clinical and technical users;
c. Use RESTful APIs for interoperability with EHRs, RPM systems, and diagnostic services;
d. Provide ECG editing tools, rhythm markup capabilities, and cardiologist review workflows.

ZBPro Diagnostic is currently validated for use in the Google Chrome browser, while Cardiologs offers broader cross-platform compatibility, including support for Safari and iOS environments. This distinction affects user workflow preferences but not the core diagnostic capabilities.

All observed differences are mitigated through ZBPro's labeling, risk controls, and software safeguards. The system's limited scope, focused on adult Holter patients using defined input vectors, does not rely on expanded device compatibility and is substantially equivalent.

In summary, while the two platforms differ in input generalization and architectural approach, these differences do not alter the shared fundamental technology purpose: ECG rhythm analysis for Holter monitoring. ZBPro Diagnostic achieves equivalent clinical functionality within its labeled scope and is therefore substantially equivalent in its technological characteristics to the predicate device.

5.11 Summary of Performance Data

Performance tests have been performed in compliance with the following recognized consensus standards:

- AAMI ANSI IEC 62304 2006 - Medical device software - Software life-cycle processes
- IEC 62366-1 Edition 1.0 2015-02 - Medical devices - Application of usability engineering to medical devices.
- AAMI ANSI EC57:2012 - Testing and Reporting Performance Results of Cardiac Rhythm And ST-Segment Measurement Algorithms
- AAMI ANSI IEC60601-2-47:2012 - Medical Electrical Equipment - Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems

5.12 Software verification and validation

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. All clinical input requirements were validated against a gold standard. No residual anomalies appeared during verification and software validation tests. General usability tests, analyzing the users' ability to import, display, store, analysis, distribute, and manage ECG data, were performed by certified cardiovascular technicians and met all requirements. All software validation testing was completed successfully and met all requirements.

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, ZBPro Diagnostic has been shown to be substantially equivalent to the cited predicate.

Usability of ZBPro Diagnostic was tested throughout development, validating the effectiveness of risk control measures associated with the user interface. ZBeats conducted usability tests of the ZBPro user interface with Certified Cardiovascular Technicians to evaluate the usability of the design, labeling and risk. The protocols cover the testable technical requirements relevant to the user interface as described in the User Interface Specification.

Performance validation testing included comprehensive rhythm classification analyses on an adjudicated database in accordance with ANSI/AAMI EC57 and IEC 60601-2-47 reporting conventions, as detailed in the ZBPro Diagnostic Performance Validation Report. Additional noise stress testing using the ZBPro Noise Stress Testing (ZNST) database was conducted to evaluate algorithm robustness under degraded signal conditions.

5.13 Conclusion

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, ZBPro Diagnostic has been shown to be substantially equivalent to the cited predicate.