December 16, 2025

prolaio, Inc.
George Allen Hides
Vice President, Regulatory, Quality, and Clinical
230 W Monroe, Unit 2560
Chicago, Illinois 60606

Re: K252204
Trade/Device Name: prolaio eVO2peak Module (Version 1.0)
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: PPW
Dated: December 1, 2025
Received: December 1, 2025

Dear George Allen Hides:

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,

Stephen C. Browning -S

LCDR Stephen Browning
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

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)*
K252204

Device Name
prolaio eVO2max Module (Version 1.0)

Indications for Use *(Describe)*

The prolaio eVO2peak Module (Version 1.0) is an all-software medical device intended to be used for estimating peak oxygen consumption (eVO2peak (mL/kg/min)) in adult patients for whom such VO2 Peak cardiopulmonary functional testing is desired.

The prolaio eVO2peak Module uses as inputs: demographic data and single-lead electrocardiogram (sampled at least 125 Hz) and triaxial accelerometry data (sampled at 50 Hz) from qualified third-party FDA-cleared wearable medical sensors from patients carrying out activities of daily living.

The prolaio eVO2peak Module is intended to provide information as an adjunctive aid in the clinical evaluation of patients by qualified clinicians who have the responsibility for interpreting its significance in connection with other standard of care clinical findings.

The prolaio eVO2peak Module is not intended to be used as a diagnostic, for active patient monitoring, to be solely relied upon for determining patient status, or as an alarm device.

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

DATE PREPARED

December 15, 2025

SUBMITTER

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Phone: (855) 869-9054

CONTACT

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This 510(k) Summary has been prepared in accordance with CFR 21 Part 807.92.

DEVICE

Category	Description
Device Trade Name	prolaio eVO2peak Module (Version 1.0)
Common Name	Adjunctive Cardiovascular Status Indicator
Classification Name	Adjunctive Cardiovascular Status Indicator
Class	2
Regulation Number	21 CFR§870.2200
Product Code	PPW

PREDICATE DEVICE

Category	Description
Device Trade Name	CipherOx CRI M1 (K173929)
Common Name	Adjunctive Cardiovascular Status Indicator
Classification Name	Adjunctive Cardiovascular Status Indicator
Class	2
Regulation Number	21 CFR§870.2200
Product Code	PPW
Note	The predicate has not been subject to a design-related recall.

DEVICE DESCRIPTION

The prolaio eVO2peak Module is a software-only Class II SaMD Python library. It processes stored physiologic data—single-lead ECG and triaxial accelerometry. The module applies a locked deep-learning model trained against reference VO2 Peak from cardiopulmonary exercise test (CPET). The module returns mean eVO2peak and contextual information allowing clinicians to use eVO2peak in concert with other clinical signs and parameters.

INDICATIONS FOR USE

The prolaio eVO2peak Module (Version 1.0) is an all-software medical device intended to be used for estimating peak oxygen consumption (eVO2peak (mL/kg/min)) in adult patients for whom such VO2 Peak cardiopulmonary functional testing is desired.

The prolaio eVO2peak Module uses as inputs: demographic data and single-lead electrocardiogram (sampled at least 125 Hz) and triaxial accelerometry data (sampled at 50 Hz) from qualified third-party FDA-cleared wearable medical sensors from patients carrying out activities of daily living.

The prolaio eVO2peak Module is intended to provide information as an adjunctive aid in the clinical evaluation of patients by qualified clinicians who have the responsibility for interpreting its significance in connection with other standard of care clinical findings.

The prolaio eVO2peak Module is not intended to be used as a diagnostic, for active patient monitoring, to be solely relied upon for determining patient status, or as an alarm device.

INTENDED USE

Intended Use and Indications for Use are the same.

PREDICATE DEVICE COMPARISON

Device Functionality	Flashback Technologies CipherOx CRI M1	prolaio eVO2peak Module (Version 1.0)	Comments
Comparison	Traditional 510(k) Predicate	Traditional 510(k) Candidate Device	—
Manufacturer	Flashback Technologies	prolaio Inc.	—
510(k) Number	K173929	K252204	—
Classification	Class 2 21CFR§2200 Adjunctive Cardiovascular Status Indicator	Class 2 21CFR§2200 Adjunctive Cardiovascular Status Indicator	Same
Product Code	PPW	PPW	Same
Intended Use	The CipherOx™ CRI M1 is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (measured by an SpO2 sensor), and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia. For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings. CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by qualified medical providers as an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.	The prolaio eVO2peak Module (Version 1.0) is an all-software medical device intended to be used for estimating peak oxygen consumption (eVO2peak (mL/kg/min)) in adult patients for whom such VO2Max cardiopulmonary functional testing is desired. The prolaio eVO2peak Module uses as inputs: demographic data and single-lead electrocardiogram (sampled at least 125 Hz) and triaxial accelerometry data (sampled at 50 Hz) from qualified third-party FDA-cleared wearable medical sensors from patients carrying out activities of daily living. The prolaio eVO2peak Module is intended to provide information as an adjunctive aid in the clinical evaluation of patients by qualified clinicians who have the responsibility for interpreting its significance in connection with other standard of care clinical findings. The prolaio eVO2peak Module is not intended to be used as a diagnostic, for active patient monitoring, to be solely relied upon for determining patient status, or as an alarm device.	Similar Estimates cardiovascular parameter of clinical interest Adult population Used by qualified medical professionals Adjunctive aid for retrospective analysis Not a diagnostic, alarm device, not for active patient monitoring, not to be solely relied upon to make clinical decisions

Device Functionality	Flashback Technologies CipherOx CRI M1	prolaio eVO2peak Module (Version 1.0)	Comments
Level of Concern	Moderate[1]	Basic Documentation Level[1]	Same Same software documentation level
Environment of Use	Hospital and prehospital settings	Ambulatory Settings	Same
Biosensor Requirements	Nonin non-invasive, finger-worn, pulse ox sensor	Non-invasive chest-worn, single-lead ECG biosensor with ECG 125 Hz or higher and triaxial accelerometer 50 Hz or higher	Similar Non-invasive commercial medical biosensor devices provide input to computational algorithm for analysis
Cardiovascular Parameter	SpO2 Pulse Rate CRI™ Algorithm	eVO2peak	Similar Different metrics but both intended to estimate clinical physiologic cardiovascular parameters
Software	Yes – CRI™ Algorithm The CRI™ algorithm trends intravascular volume using non-invasive arterial pulsatile waveform signals by continuously comparing extracted waveforms to a reference model. CipherOx™ CRI system operates on the photoplethysmograph (PPG) waveform used in pulse oximetry to estimate CRI.	Yes – eVO2peak eVO2peak estimates peak oxygen consumption.	Same
Display	Yes. M1 User Interface module is a small, portable, battery-powered multiparameter monitor	No	Similar eVO2peak Module does not include an interface or display but its outputs can be integrated into such an external system for display
Patient Population	Adult (19 – 36 yrs)	Adult	Same
Alarm	No	No	Same
Active Patient Monitoring	No	No	Same

[1] "Minor", "Moderate", "Major" Levels of Concern has been replaced with "Basic" or "Enhanced" Documentation Levels in *Guidance for Industry – Content of Premarket Submissions for Device Software Function* (2023).

A detailed Substantial Equivalence Table is available in the submission, comparing device characteristics including algorithmic methodology, input/output data types, performance metrics, system integration pathways, and risk control measures.

SPECIAL CONTROLS

Adjunctive cardiovascular status indicator devices include several special controls, as follows:

Control	Evidence
Software description, verification, and validation based on comprehensive hazard analysis must be provided.	
Full characterization of technical parameters of the software, including any proprietary algorithm(s)	Software Description
Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications	Software Description
Specification of acceptable incoming sensor data quality control measures	Software Description
Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports	Risk Analysis Usability Assessment
Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling.	Device Description
Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.	Usability Assessment
Clinical data must be provided in support of the intended use.	
Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner	Validation Report
The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified	Validation Report
Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range;	Validation Report
Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment	Validation Report
Labeling	
The type of sensor data used, including specification of compatible sensors for data acquisition	User Guide and Installation Manual & User About Page
A description of what the device measures and outputs to the user	User Guide and Installation Manual & User About Page

Control	Evidence
Warnings identifying sensor reading acquisition factors that may impact measurement results	User Guide and Installation Manual & User About Page
Guidance for interpretation of the measurements, including warning(s) specifying adjunctive use of the measurements	User Guide and Installation Manual & User About Page
Key assumptions made in the calculation and determination of measurements	User Guide and Installation Manual & User About Page
The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance	User Guide and Installation Manual
A detailed description of the patients studied in the clinical validation (*e.g.,* age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study	User About Page

PERFORMANCE DATA

Risk Management:

The prolaio peak Module underwent risk analysis per ISO 14971. All residual risks post-mitigation were evaluated as acceptable.

Cybersecurity:

Cybersecurity testing was conducted under the principles in FDA's 2023 Cybersecurity Premarket Guidance. The module includes encryption, access control, input validation, and logging as part of its secure product development framework. All residual risks post-mitigation were evaluated as acceptable.

Human Factors Engineering (HFE):

Although the device lacks a user interface, HFE principles under IEC 62366 and FDA's 2016 Applying Human Factors and Usability Engineering to Medical Devices were applied to ensure safe integration and interpretation of outputs by clinical users. Documentation includes instructions for integration and intended context of use. Evaluation supported that device users could safely use the device.

AI/ML Compliance:

The module was developed in accordance with FDA's Good Machine Learning Practice (GMLP) principles. Training and validation datasets were diverse and clinically representative of the target population. The algorithm is locked and does not perform autonomous updates.

Software V&V

Verification and validation activities per IEC 62304 confirmed functional performance, scalability, and compatibility to ensure that the use of the software fulfils the intended use without causing any unacceptable risks.

Clinical Validation:

Validation of prolaio eVO2peak was performed using data from patients undergoing cardiopulmonary exercise tests (CPET) in a clinical study including multiple centers in the United States. Overall, 228 patients were enrolled in multiple regions and were demographically diverse and representative of the intended population. Performance of prolaio eVO2peak met the target accuracy, reliability/consistency, and bias criteria.

Results	**Overall [95%CI]**	**Bike Modality [95%CI]**
Mean Error (Bias) (mL/kg/min)	1.47 [0.55, 2.27]	0.97 [0.01, 1.96]
Mean Absolute Error (mL/kg/min)	4.39 [3.82, 4.91]	4.07 [3.52, 4.69]

CONCLUSIONS

The results from risk management, design control, and clinical testing support that the prolaio eVO2peak Module is substantially equivalent to the predicate device. The proposed device does not raise new questions of safety or effectiveness compared to the predicate, or from differences to the predicate, for the proposed indications for use.