February 12, 2025

Etiometry Inc.
Tim Hanson
VP QA RA
280 Summer St. Fourth Floor
Boston, Massachusetts 02210

Re: K241479
Trade/Device Name: Etiometry Platform (DAV 5.4 RAE 9.2)
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: PPW,
Dated: May 23, 2024
Received: May 24, 2024

Dear Tim Hanson:

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241479

Device Name
Etiometry Platform (DAV 5.4 RAE 9.2)

Indications for Use *(Describe)*
The Etiometry Platform™ software features the Data Aggregation & Visualization software module version 5.4 and the Risk Analytics Engine software module version 9.2.

The Data Aggregation & Visualization software module is intended to record and display multiple physiological parameters of adult, pediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification, nor is it intended to control any of the independent bedside devices to which it is connected. The software module is intended to be used by healthcare professionals for the following purposes:

To remotely consult regarding a patient's status and
To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

The Data Aggregation & Visualization software module can display numeric physiologic data and waveforms captured by other medical devices:

Airway flow, volume, and pressure
Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
Bispectral index (BIS, signal quality index, suppression ratio)
Cardiac Index
Cardiac output
Central venous pressure
Cerebral perfusion pressure
End-tidal CO2
Heart rate
Heart rate variability
Intracranial pressure
Left atrium pressure
Oxygen saturation (intravascular, regional, SpO2)
Premature ventricular counted beats
Pulmonary artery pressure (systolic, diastolic, and mean)
Pulse pressure variation
Pulse Rate
Respiratory rate
Right atrium pressure
Temperature (rectal, esophageal, tympanic, blood, core, nasopharyngeal, skin)
Umbilical arterial pressure (systolic, diastolic, and mean)
Electrocardiogram
Plethysmograph

The Data Aggregation & Visualization software module can display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid.
The Data Aggregation & Visualization software module can display information captured by the Risk Analytics Engine software module.

The Risk Analytics Engine software module calculates four indices: the IDO2 Index™ for inadequate delivery of oxygen, the IVCO2 Index™ for inadequate ventilation of carbon dioxide, the ACD Index™ for acidemia, and the HLA Index™ for hyperlactatemia.

The IDO2 Index is indicated for use by health care professionals with post-surgical patients 0 to 12 years of age and weighing 2 kg or more under intensive care and patients 18 years of age or older under intensive care and not on Mechanical Circulatory Support. The IDO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation & Visualization software module. When the IDO2 Index is increasing, it means that there is an increasing risk of inadequate oxygen delivery, and attention should be brought to the patient. The IDO2 Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The IVCO2 Index is indicated for use by healthcare professionals with invasively ventilated patients 0 to 12 years of age under intensive care. The IVCO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation and Visualization software module. When the IVCO2 Index is increasing, it means that there is an increasing risk of inadequate carbon dioxide ventilation, and attention should be brought to the patient. The IVCO2 Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The ACD Index is indicated for use by health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The ACD Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation and Visualization software module. When the ACD Index is increasing, it means that there is an increasing risk of acidemia, and attention should be brought to the patient. The ACD Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The HLA Index is indicated for use by health care professionals with post-surgical patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The HLA Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation & Visualization software module. When the HLA Index is increasing, it means that there is an increasing risk of hyperlactatemia, and attention should be brought to the patient. The HLA Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.

WARNINGS:

Do not use the application as an active patient monitoring system.
Do not use the application to replace any part of the hospital's device monitoring.
Do not rely on the application as the sole source of patient status information.
Do not use any of the indices as a substitute for taking blood samples.
Do not use the IDO2 Index for adult patients on Mechanical Circulatory Support.
The indices present qualitative and potentially imperfect information about the patient's condition, and in certain scenarios, the indices may contradict each other.
The primary data should be reviewed as part of standard patient evaluations, and no decisions should be solely based on the indices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Feb 11, 2025

This 510(k) summary has been prepared following Title 21 CFR §807.92 and FDA's guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)" July 28, 2014.

K241479

1. Contact Details

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2. Device Name

Item	Description
Device Trade Name	Etiometry Platform™ (DAV 5.4 RAE 9.2)
Common Name	Adjunctive Cardiovascular Status Indicator
Classification Name	Adjunctive Cardiovascular Status Indicator
Regulation Number	870.2200
Product Code(s)	PPW

3. Legally Marketed Predicate Devices

The predicate devices are the Etiometry Platform, cleared under K223578 and K213423, with the PPW product code.

4. Device Description Summary

The Etiometry Platform allows ICU clinicians and quality improvement teams to aggregate data from multiple sources, store it in a database for analysis, and view the streaming data. The platform features include:

- Adjunctive status indicators
- Customizable display of physiologic parameters over the entire patient stay
- Configurable annotation
- Web-based visualization that may be used on any standard browser
- Minimal IT footprint
- Software-only solution – no new bedside hardware required
- Highly reliable and robust operation
- Auditable data storage

5. Intended Use/Indications For Use

The Etiometry Platform™ software features the Data Aggregation & Visualization software module version 5.4 and the Risk Analytics Engine software module version 9.2.

The Data Aggregation & Visualization software module is intended to record and display multiple physiological parameters of adult, pediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification, nor is it intended to control any of the independent bedside devices to which it is connected. The software module is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding a patient's status and
- To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

The Data Aggregation & Visualization software module can display numeric physiologic data and waveforms captured by other medical devices:

- Airway flow, volume, and pressure
- Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
- Bispectral index (BIS, signal quality index, suppression ratio)
- Cardiac Index
- Cardiac output
- Central venous pressure
- Cerebral perfusion pressure
- End-tidal CO2
- Heart rate
- Heart rate variability
- Intracranial pressure
- Left atrium pressure
- Oxygen saturation (intravascular, regional, SpO2)
- Premature ventricular counted beats

- Pulmonary artery pressure (systolic, diastolic, and mean)
- Pulse pressure variation
- Pulse Rate
- Respiratory rate
- Right atrium pressure
- Temperature (rectal, esophageal, tympanic, blood, core, nasopharyngeal, skin)
- Umbilical arterial pressure (systolic, diastolic, and mean)
- Electrocardiogram
- Plethysmograph

The Data Aggregation & Visualization software module can display laboratory measurements, including arterial and venous blood gases, complete blood count, and lactic acid. The Data Aggregation & Visualization software module can display information captured by the Risk Analytics Engine software module.

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The IVCO2 Index is indicated for use by healthcare professionals with invasively ventilated patients 0 to 12 years of age under intensive care. The IVCO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation and Visualization software module. When the IVCO2 Index is increasing, it means that there is an increasing risk of inadequate carbon dioxide ventilation, and attention should be brought to the patient. The IVCO2 Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The ACD Index is indicated for use by health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The ACD Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation and Visualization software module. When the ACD Index is increasing, it means that there is an increasing risk of acidemia, and attention should be brought to the patient. The ACD Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The HLA Index is indicated for use by health care professionals with post-surgical patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The HLA Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the Data Aggregation & Visualization software module. When the HLA Index is increasing, it means that there is an increasing risk

of hyperlactatemia, and attention should be brought to the patient. The HLA Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.

WARNINGS:

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- Do not use the IDO2 Index for adult patients on Mechanical Circulatory Support.
- The indices present qualitative and potentially imperfect information about the patient's condition, and in certain scenarios, the indices may contradict each other.
- The primary data should be reviewed as part of standard patient evaluations, and no decisions should be solely based on the indices.

6. Indications For Use Comparison

The indications for use are the same.

7. Technological Comparison

The device has the same technological characteristics as the predicate devices identified above. The subject device unifies the predicate devices' IDO2 Index (pediatrics and adults).

8. Non-Clinical And/Or Clinical Tests Summary

Documentation was provided, following the FDA guidance document Software as a Medical Device (SAMD): Clinical Evaluation to support the software with a moderate level of concern and to confirm and provide objective evidence that it was correctly constructed. Cybersecurity information was provided following the FDA guidance document Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Evaluations were completed to demonstrate the consistency of the output, which is representative of the range of data sources and data quality likely to be encountered.

Documentation was provided, following the FDA guidance document Software as a Medical Device (SAMD): Clinical Evaluation to support the software with a moderate level of concern and yield a clinically meaningful output associated with the target use of the output in the target health care situation or condition identified in the definition statement. A model produces the adjunctive status indicators, designed based on principles of physiology, with parameters chosen to reflect those specified in the medical literature. Test datasets were used to evaluate the impact of the changes during the development process. Validation datasets were used after development was complete to validate performance using independent data. The adjunctive status indicators were validated utilizing data from different clinical sites in the US. The clinical study data were obtained using the platform. No adverse effects or complications were noted. The adjunctive status indicators were retrospectively computed on all de-identified patients. The adjunctive status indicators were evaluated against the same acceptance criteria as the predicate device, i.e., discriminatory power, range utilization, resolution/ limitation, and robustness. The validation dataset included the distribution of 4721 points among 779 patients

(253 females - 32%, 526 males - 68%). All results met the same acceptance criteria as the predicate device, i.e., discriminatory power, range utilization, resolution/limitation, and robustness.

9. Conclusion

In conclusion, the subject device has demonstrated a safety and effectiveness profile substantially equivalent to the identified predicate devices. Based on the provided testing and performance data, the device does not raise new questions of safety or effectiveness and is suitable for its intended use.