June 22, 2022

Etiometry, Inc.
Tim Hanson
VP of RA/QA
280 Summer St, 4th Floor
Boston, Massachusetts 02210

Re: K213230
Trade/Device Name: T3 Platform Software
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: PPW
Dated: September 27, 2021
Received: September 29, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

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)*
K213230

Device Name
T3 Platform™ software

Indications for Use *(Describe)*

The T3 Platform™ software features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 8.0.

The T3 Data Aggregation & Visualization software module is intended for the recording and display of multiple physiological parameters of the adult, pediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification or waveform display, 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 T3 Data Aggregation & Visualization software module can display numeric physiologic data 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)

The T3 Data Aggregation & Visualization software module can display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid. T3 Data Aggregation & Visualization software module can display information captured by the T3 Risk Analytics Engine software module.

The T3 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. The IDO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 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 health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The IVCO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 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 T3 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 T3 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 T3 Platform software as an active patient monitoring system.
- Do not use the T3 Platform software to replace any part of the hospital's device monitoring.
- Do not rely on the T3 Platform software as the sole source of patient status information.
- Do not use any of the T3 Platform indices as a substitute for taking blood samples.
- The indices present qualitative and potentially imperfect information of 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.

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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.

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9.0 510(k) Summary

May 13, 2022

This 510(k) summary has been prepared in accordance with 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

9.1 510(k) Submitter

Timothy Hanson, VP of Regulatory Affairs and Quality Assurance
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Boston, MA 02210
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9.2 Device

Item	Description
Device Trade Name	T3 Platform™ software
Device Common/Usual Name	Clinical Decision Support Software (without alarms)
Classification Name	Adjunctive cardiovascular status indicator
Classification Number	870.2200
Regulatory Class	Class II with special controls - the primary code is PPW: The adjunctive cardiovascular status indicator is a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

Table 97: Device Information

9.3 Predicate Devices

The primary predicate device is the CipherOx CRI, cleared under DEN160020, and the supportive predicate device is the T3 Platform™ software featuring the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 6.0, cleared under K202306. These predicates have not been subject to a design-related recall. No reference devices were used in this submission.

9.4 Device Description

The Tracking, Trajectory, Trigger *(T3)* intensive care unit software solution allows clinicians and quality improvement teams in the ICU to aggregate data from multiple sources, store it in a database for analysis, and view the streaming data. System features include:

- Adjunctive status indicators
- Customizable display of physiologic parameters over 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

9.5 Indications for Use

The T3 Platform™ software features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 8.0.

The T3 Data Aggregation & Visualization software module is intended for the recording and display of multiple physiological parameters of the adult, pediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification or waveform display, 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 T3 Data Aggregation & Visualization software module can display numeric physiologic data 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)

The T3 Data Aggregation & Visualization software module can display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid.
The T3 Data Aggregation & Visualization software module can display information captured by the T3 Risk Analytics Engine software module.

The T3 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. The IDO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 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 health care professionals with invasively ventilated patients 0 to 12 years of age and weighing 2 kg or more under intensive care. The IVCO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 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 T3 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 T3 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 T3 Platform™ software as an active patient monitoring system.
- Do not use the T3 Platform™ software to replace any part of the hospital's device monitoring.
- Do not rely on the T3 Platform™ software as the sole source of patient status information.
- Do not use any of the T3 Platform™ indices as a substitute for taking blood samples.
- The indices present qualitative and potentially imperfect information of 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.

9.6 Comparison of Technological Characteristics with the Predicate Device

The primary predicate device, having the product code PPW, is intended for use as a multiparameter monitor that uses sensor technology to measure a specific parameter. The devices that fall under this regulation product code (Adjunctive cardiovascular status indicator 21 CFR 870.2200) do not have alarms and do not have a set decision point, matching the functionalities of the subject device. The regulation product code of the primary predicate device includes special controls that were applied to the subject T3 Platform™ software. The regulation product codes between the subject T3 Platform™ software and supportive predicate T3 Platform™ software were unchanged. The subject T3 Platform™ software and supportive predicate T3 Platform™ software have the same Intended Use adding the ACD and HLA Indices.

The subject and predicate devices differ with respect to several technological features. (see Table 98).

Feature/Improvement	Description
ACD Index	The underlying physiology model of the Risk Analytics Engine (version 8.0) has been updated to afford the computation of a new index which is a measure of the likelihood that an arterial blood gas will indicate acidemia defined as arterial pH less than 7.25. The new index has been subject to the same performance testing as the predicate IDO2 and IVCO2 indices. Specifically, the enclosed 510(k) application includes performance test results using clinical data, covering the indicated patient age range: 0 to 12 years of age.

Feature/Improvement	Description
HLA Index	Additional changes to the underlying physiology model of the Risk Analytics Engine (version 8.0) enable the computation of a second new index which is a measure of the likelihood that a laboratory result will indicate hyperlactatemia defined as whole blood lactate level concentration above 4 mmol / L. The new index has been subject to the same performance testing as the predicate IDO2 and IVCO2 indices. Specifically, the enclosed 510(k) application includes performance test results using clinical data, covering the indicated patient age range: 0 to 12 years of age.
Tidal Volume to Minute Ventilation Input Change	The Risk Analytics Engine (version 8.0) employs direct measurements of minute ventilation provided by the ventilator instead of relying on the indirect calculation of minute ventilation accomplished by multiplying tidal volume and respiratory rate.
Removal of EtCO2 as required input for IVCO2	The IVCO2 Index included as part of the Risk Analytics Engine (version 8.0) no longer requires EtCO2 to be available as part of the minimum data. More specifically, the software utilizes blood gas measurements, arterial or venous pCO2 collected at a minimum of once every 12 hours, interchangeably with EtCO2 measurements. When blood gases are not available, the software processes available EtCO2 measurements to satisfy the minimum data set required as was the case in previous cleared releases.
Continuous Performance Assessment	In order to continually monitor the performance of the Risk Indices in different operating environments and clinical settings, the Continuous Performance Assessment module (CPA) was developed, which periodically computes all critical performance metrics for a site and reports these metrics via email to the Etiometry Support team. If the CPA tool indicates that the performance of the Risk indices at a particular site is out of specification, the support team can use this information to take action, investigate the root cause, and apply mitigation measures as needed.
Repair to the Risk Algorithm Engine response to Reinitialization	As part of the required behavior, when a Risk index is initialized on an individual patient, the index is not reported before the minimum data set is achieved and the index is calibrated (5 minutes post initialization). This behavior was not propagated to the rare instances of algorithm reinitialization, which did not match the original requirement. The Risk Analytics Engine (version 8.0) provides a repair that satisfies the original requirement.

Feature/Improvement	Description
IVCO2 Index patient population	The patient population in the indications for use was expanded from 29 days to 12 years of age to 0 to 12 years of age for the IVCO2 Index in the Risk Analytics Engine (version 8.0).

Table 98: Summary of Changes

9.7 Summary of Non-Clinical Performance Testing

Software documentation was provided in accordance with the 2017 FDA guidance document *Software as a Medical Device (SAMD): Clinical Evaluation* section 5.3 Analytical / Technical Validation of a SaMD to support device software with a moderate level of concern and to confirm and provide objective evidence that the software was correctly constructed.

Cybersecurity information was provided in accordance with the 2014 FDA guidance document *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

Additional summative evaluations were completed to demonstrate the consistency of the output, representative of the range of data sources and data quality, likely to be encountered.

Human factors testing was used to support that device users could safely use the device.

9.8 Summary of Clinical Performance Testing

All of the four indices are a product of a model-based approach to risk estimation. The approach is designed based on principles of physiology, and parameters are chosen to reflect those specified in the medical literature and employed development testing data sets and validation sets. Development testing sets are used to evaluate the impact of the development changes during the development process. Validation sets are then used after all development is complete to validate that performance holds on an independent data set.

The four indices were validated utilizing validation sets that included data from eleven different clinical sites in the US. The clinical study data were obtained by the T3 Platform software. No adverse effects and complications were noted. The indices were retrospectively computed on all de-identified patients. The new indices were evaluated against the same acceptance criteria as the supportive predicate device, being discriminatory power, range utilization, resolution/limitation, and robustness.

A patient cohort was used to validate the HLA Index. The distribution of the points included in the HLA study among the participating centers totaling 58,168 whole blood lactate measurements from 3,496 patients was included in that validation data set. The demographics were 31% neonates, 36% infants, and 33% children.

A patient cohort was used to validate the ACD Index. The distribution of the points included in the ACD study among the participating centers totaling 24,431 arterial blood pH measurements from 1,858 patients was included in the validation data set. The demographics were 40% neonates, 34% infants, and 26% children.

Additionally, subpopulations studies (neonates, infants, and children) under each of the HLA study and ACD study were completed.

All results met acceptance criteria for discriminatory power, range utilization, resolution/limitation, and robustness.

Software documentation was provided in accordance with the 2017 FDA guidance document *Software as a Medical Device (SAMD): Clinical Evaluation* section 5.3 Analytical / Technical Validation of a SaMD to support device software with a moderate level of concern and to yield a clinically meaningful output associated to the target use of the output in the target health care situation or condition identified in the definition statement.

9.9 Summary

Based on the clinical performance, the T3 Platform™ software was found to have a safety and effectiveness profile that is similar to the predicate devices.

9.10 Conclusions

Substantial equivalence of the T3 Platform™ software is demonstrated through performance testing and clinical evaluation and through the special controls of the PPW product code of the primary predicate device. The T3 Platform™ software has the equivalent design, features, and functionality as the supportive predicate T3 Platform™ software with few exceptions. These exceptions do not affect the safety or effectiveness of the system. No new questions of safety or effectiveness are raised as a result of the differences when compared to the predicate devices. The software verification demonstrates that the T3 Platform™ software performs as intended in the specified use conditions. The clinical evaluation demonstrates that the T3 Platform™ software performs comparably to the predicate devices that are currently marketed for the same intended use.