January 6, 2023

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

Re: K213423
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: October 15, 2021
Received: October 20, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213423

Device Name
The 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 Adult Risk Analytics Engine software module version 1.0.

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 Adult Risk Analytics Engine software module.

The T3 Adult Risk Analytics Engine software module calculates the Adult IDO2 Index for inadequate delivery of oxygen. The Adult IDO2 Index is indicated for use by health care professionals with post-surgical patients 18 years of age or older under intensive care and not on Mechanical Circulatory Support. The Adult 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 Adult 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 Adult 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.

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.
- Do not use the Adult IDO2 Index for patients on Mechanical Circulatory Support

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

4.0 510(k) Summary

Dec 7, 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

4.1 510(k) Submitter

Timothy Hanson, VP of Regulatory Affairs and Quality Assurance
280 Summer St., 4th Floor
Boston, MA 02210
Tel: 857.366.9333 ext. 2020
Email: THanson@etiometry.com

4.2 Device

Item	Description
Device Trade Name	T3 Platform™ software (T3 Data Aggregation & Visualization software module version 5.0 and T3 Adult Risk Analytics Engine software module version 1.0)
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 7: Device Information

4.3 Predicate Devices

The 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 8.0, cleared under K213230.

4.4 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:

- 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

4.5 Indications for Use

The T3 Platform™ software features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Adult Risk Analytics Engine software module version 1.0.

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 Adult Risk Analytics Engine software module.

The T3 Adult Risk Analytics Engine software module calculates the Adult IDO2 Index for inadequate delivery of oxygen. The Adult IDO2 Index is indicated for use by health care professionals with post-surgical patients 18 years of age or older under intensive care and not on Mechanical Circulatory Support. The Adult 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 Adult 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 Adult 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.

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.
- Do not use the Adult IDO2 Index for patients on Mechanical Circulatory Support

4.6 Comparison of Technological Characteristics with the Predicate Device

The subject and predicate T3 Platform™ software have the same Intended Use, brining attention to patients and providing an IDO2 Index, but for different patient populations. The 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 and predicate devices differ with respect to several technological features. (see Table 8).

Feature/Improvement	Description
Replacing the Risk Analytics Engine with the Adult Risk Analytics Engine with Adult IDO2 Index	The subject device, the T3 Platform software for adults is a standalone application that was abstracted as an instance from the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 8.0 cleared under K213230. The Risk Analytics Engine module was modified to become the Adult Risk Analytics Engine software module, version 1.0, with the Adult IDO2 Index and compatible with the T3 Data Aggregation & Visualization software module version 5.0. Adult Risk Analytics Engine is responsible for the continuous computation in near-real-time of the likelihood that a patient, 18 years of age or older, is experiencing Inadequate Delivery of Oxygen defined as the Adult IDO2 index. Adult Risk Analytics Engine version 1.0 employs the same model of human physiology as the one utilized in Risk Analytics Engine version 8.0 cleared under K213230 for the computation of the IDO2 index in pediatric patients (0 to 12 years of age), however, the physiology model has been modified to extend the age-based parameterization. Adult Risk Analytics Engine version 1.0 is also different from Risk Analytics Engine version 8.0 with respect to the IDO2 index being computed as the likelihood of mixed venous oxygen saturation that is below a single non-configurable threshold of 50%.

Table 8: Summary of Changes

4.7 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.

4.8 Summary of Clinical Performance Testing

The adult IDO2 Index was validated using clinical datasets. The results from Performance Testing - Clinical Evaluation met acceptance criteria for discriminatory power, range utilization, and robustness.

The adult IDO2 Index was validated utilizing a validation set that included data from different clinical sites in the US. The clinical study data were obtained by the T3 Platform software. No adverse effects or complications were noted. The indices were retrospectively computed on all de-identified patients. The index was 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 Index. The distribution of the points included in the study among the participating centers totaling 4251 mixed venous oxygen saturation measurements from 634 patients were included in that validation data set. The demographics were 69% male, 31% females.

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.

4.9 Summary

The T3 Platform™ software was found to have a safety and effectiveness profile that is substantial equivalent to the predicate device.

4.10 Conclusions

Substantial equivalence of the T3 Platform™ software has been demonstrated. The T3 Platform™ software has the equivalent design, features and functionality as the predicate T3 Platform™ software with few exceptions and these exceptions do not affect the safety or effectiveness of the system. No new questions of safety or effectiveness were raised as a result of the differences when compared to the predicate device, and the data provided in the submission show that the subject device is substantially equivalent to the legally-marketed predicate device.