July 7, 2023

Etiometry, Inc.
Timothy Hanson
VP of Regulatory Affairs and Quality Assurance
280 Summer St.,
4th Floor
Boston, Massachusetts 02210

Re: K223578
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: June 7, 2023
Received: June 8, 2023

Dear Timothy 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)*
K223578

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 Risk Analytics Engine software module version 9.0.

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 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.

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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Jul 3, 2023

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

# 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

# 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 1: Device Information

# 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. The predicate has not been subject to a design-related recall. No reference devices were used in this submission.

# 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 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 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 9.0.

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
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- Cardiac Index
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- 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.

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The IVCO2 Index™ is indicated for use by health care 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 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 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 Comparison of Technological Characteristics with the Predicate Device

The subject T3 Platform™ software and predicate T3 Platform™ software have the same intended use. They differ with respect to the following technological features (see Table 2).

| Feature/Improvement | Description |
|---|---|
| **Removal of 2 kg Restriction from the IVCO2 Index Indications For Use** | The restriction that the IVCO2 Index™ is indicated for use on patients weighing 2 kg or more has been removed. |

Table 2: Summary of Changes

## 7 Summary of Non-Clinical Performance Testing

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 the 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*.

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

## 8 Summary of Clinical Performance Testing

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 the

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.

The adjunctive status indicators are produced by a model-based approach. The model-based approach is designed based on principles of physiology with parameters chosen to reflect those specified in the medical literature. Development test sets are used to evaluate the impact of the development changes during the development process. Validation sets are used after development is complete to validate performance using independent data sets.

The adjunctive status indicators were validated utilizing validation sets 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 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. Two patient cohorts were used to validate the IVCO2 Index. The first performance analysis of the IVCO2 Index used a cohort consisting of neonatal ICU patients. The analysis contained data from two level IV regional NICUs. In total, 1108 PaCO2 measurements from arterial blood gases among 180 patients were included in the NICU validation data set. The second performance analysis of the IVCO2 Index used a cohort consisting of non-NICU patients to evaluate the impact of technical changes made to the software, to accommodate patients weighing < 2kg found in a NICU, on patients not found in the NICU. In total, 29,841 PaCO2 measurements from arterial blood gases among 2090 patients were included in the non-NICU validation data set. The overall demographics were 42% neonates, 32% infants, and 26% children. 46% of the patients were female and 54% of the patients were male. All results met the same acceptance criteria as the predicate device, i.e., discriminatory power, range utilization, resolution/limitation, and robustness.

# 9 Summary

Based on the clinical performance, the subject T3 Platform™ software was found to have a safety and effectiveness profile that is similar to the predicate T3 Platform™ software, cleared under K213230.

# 10 Conclusions

Substantial equivalence of the T3 Platform™ software is demonstrated through performance testing, clinical evaluation, and special controls. The T3 Platform™ software has the equivalent design, features, and functionality as the predicate T3 Platform™ software. No new questions of safety or effectiveness were raised as a result of the differences when compared to the predicate device. 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 device that is currently marketed for the same intended use.