November 25, 2020

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

Re: K202306
Trade/Device Name: T3 Platform software
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, PLB
Dated: August 5, 2020
Received: August 14, 2020

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,

for LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K202306

Device Name
The T3 Platform™ software features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 6.0.

Indications for Use *(Describe)*
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 two indices: the IDO2 Index™ for inadequate delivery of oxygen and the IVCO2 Index™ for inadequate ventilation of carbon dioxide.

IDO2 Index™ is indicated for use by health care professionals with post-surgical patients aged zero days to twelve years

weighing 2 kg or more under intensive care. IDO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module, version 5.0 or higher. 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.

IVCO2 Index™ is indicated for use by health care professionals with invasively ventilated patients aged 29 days to 12 years weighing 2 kg or more under intensive care. IVCO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module, version 5.0 or higher. 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.

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 the IVCO2 Index as a substitute for arterial blood gases.

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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October 28, 2020

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, Director of Regulatory Affairs and Quality Assurance
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Boston, MA 02210
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4.2 Device

Item	Description
Device Trade Name	T3 Platform™ software (T3 Data Aggregation & Visualization software module version 5.0 and T3 Risk Analytics Engine software module version 6.0)
Device Common/Usual Name	Data Management Software (without alarms)
Classification Name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification Number	870.2300

Item	Description
Regulatory Class	Class II The primary code is MWI: monitor, physiological, patient (without arrhythmia detection or alarms). The secondary code is PLB: automated calculation of a summary index (or indices) based on several individual measured vital sign inputs.

Table 1: Device Information

4.3 Predicate Device

The T3 Platform™ software featuring the T3 Data Aggregation & Visualization software module version 3.3 and the T3 Risk Analytics Engine software module version 5.0, cleared under K190273.

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 Risk Analytics Engine software module version 6.0.

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)
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- Cardiac output

- Central venous pressure
- Cerebral perfusion pressure
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- Pulmonary artery pressure (systolic, diastolic, and mean)
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- Pulse Rate
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The T3 Risk Analytics Engine software module calculates two indices: the IDO2 Index™ for inadequate delivery of oxygen and the IVCO2 Index™ for inadequate ventilation of carbon dioxide.

IDO2 Index™ is indicated for use by health care professionals with post-surgical patients aged zero days to twelve years weighing 2 kg or more under intensive care. IDO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module, version 5.0 or higher. 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.

IVCO2 Index™ is indicated for use by health care professionals with invasively ventilated patients aged 29 days to 12 years weighing 2 kg or more under intensive care. IVCO2 Index™ is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module, version 5.0 or higher. 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.

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 the IVCO2 Index™ as a substitute for arterial blood gases.

4.6 Comparison of Technological Characteristics with the Predicate Device

The subject and predicate T3 Platform™ software have the same Intended Use/Indication for Use. The subject and predicate devices differ with respect to several technological features. (see Table 2).

Feature/Improvement	Description
Addition of data from regional oxygen saturation monitors as an input for the calculation of the IDO2 Index™	Data from regional oxygen saturation monitors, when available, have been added as an input to the Risk Analytics Engine module to facilitate the detection of inadequate oxygen delivery and respectively improve the performance of the IDO2 Index™. Specifically, data from regional oximetry are used as a noise proxy of mixed venous oxygen saturation which the hemodynamic model interprets in the context of other physiologic measurements to infer IDO2 value. The performance of the IDO2 Index™ was evaluated with and without regional oximetry to confirm the utility of the measurement as an input.
Measure Contributions signifying measurement inputs which have the highest contribution to an increase in the IDO2 Index™ or the IVCO2 Index™	To increase the transparency and understanding of the risk indices computed by the platform, the computations have been supplemented with an external routine which computes how either removing an existing measurement as an input (if the measurement is not in the minimum data set required for the computation of the index) or setting a measurement to what the algorithms perceive as nominal (if the measurement is part of the minimum data set) affects the individual indices. This computing routine enables assessment of the "contribution" of each available input in both the IDO2 Index™ or the IVCO2 Index™. The three measurements with the highest contribution, i.e. the measurements whose removal or setting to nominal leads to the highest drop in a particular index are then displayed as the major contributing measurements at the particular time instance.
User selectable thresholds for defining Inadequate Oxygen Delivery and Inadequate Ventilation of Carbon Dioxide	The previously cleared version of the software computed the IDO2 Index™ and the IVCO2 Index™ as the likelihood of $SvO2 < 40\%$ and $PaCO2 > 50$ mmHg respectively. Using the same computation framework, the current version enables several more thresholds that a clinical user can configure. This facilitates individualizing the indices based on patient condition or other clinical considerations.
Modification of minimum data required to compute IVCO2 Index™	The minimum set for the IVCO2 Index™ to exclude the arterial blood gases requirement.
Support for encrypted data feeds into the platform	To improve the cybersecurity of the platform, the software introduces the ability to accept encrypted data feeds from hospital data sources.
Display of complete lab panel information	The software introduces a detailed view of a plotted lab result to provide additional clinical context to the results. This allows clinicians to both contextualize lab results with physiologic data, but also with other lab results within the panel.
Embedded Standalone Platform Manual	To further ensure labeling availability and distribution, the software has embedded the complete platform manual as part of the release. Users can easy access, consult, and/or download the manual within the system.

Feature/Improvement	Description
Addition of Tele-medicine Census view in the existing User Interface	The User Interface introduces a new feature to facilitate the viewing of the status of all patients in an ICU in a single display, which can serve as a starting point for a more detailed review of individual patient information. The tool supports interpreting trends for selected variables, understanding the trajectory of patients, and supporting bedside clinicians in their decision making. For each bed in the ICU, the bed number is displayed along with the last name and age if there is currently a patient in that bed. This tool differs from the Census Overview by displaying for each patient the most recent vital signs and algorithm values in tiles containing graphs instead of a table of rows
Integration of Single Sign-on	To facilitate access to the platform, the software has an added capability to integrate with an Electronic Medical Record system (EMR). A user can navigate to display T3 patient information from the EMR with a single click, which automatically authenticates them in T3 and navigates them to the patient of interest.
Miscellaneous Updates of the Hemodynamic Model Employed to Infer the IDO2 Index™	The hemodynamic model powering the IDO2 Index™ has been updated by improving specific modeled physiologic effects such as the adaptable relationship between pulse pressure and stroke volume which now utilizes a logarithmic relationship to facilitate linear estimation. The updated IDO2 Index™ algorithm was subject to full performance clinical testing.
Addition of a Retrospective Teaching Census	To facilitate software education and training, the platform introduces the ability to collate, de-identify, and save a specific patient case in a hospital specific teaching census for use as a training resource.
Repair incorporation of incorrectly labeled SvO2 measurements into the algorithm	The software has been modified to reject measurements which may not correctly be associated with mixed or central venous oxygen saturation. The software classifies venous oxygen saturation measurements as either validated or non-validated and incorporates the measures under different conditions based on that classification.

Table 2: Summary of Changes

4.7 Performance Data

The changes to the algorithm were validated using clinical data sets. The software verification and validation testing were conducted for the subject device, and documentation was provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005. The results of this testing demonstrate that the safety and effectiveness of the subject T3 Platform™ software (subject device) are comparable to that of the predicate T3 Platform™ software (target device).

4.8 Conclusions

Substantial equivalence of the T3 Platform™ software is demonstrated through performance testing. 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 are 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.