December 8, 2019

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

Re: K190273
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: PLB, MWI
Dated: November 1, 2019
Received: November 4, 2019

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190273

Device Name
T3 Platform software

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.
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 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 3.3 or higher. When the IDO2 Index™ is elevated, it means that there is an increased 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 3.3 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.

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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November 1, 2019

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

1.0 510(k) Submitter

Timothy Hanson, Director of Regulatory Affairs and Quality Assurance
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Boston, MA 02210
Tel: 857.366.9333 ext. 2020
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2.0 Device

Device Trade Name: T3 Platform software (T3 Data Aggregation & Visualization software module version 3.3 and T3 Risk Analytics Engine software module version 5.0)
Device Common/Usual Name: Data Management Software (without alarms)
Classification Name: Cardiac monitor (including cardiotachometer and rate alarm)
Classification Number: 870.2300
Regulatory 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.

3.0 Predicate Device

The T3 Platform software 3.0 (featuring the T3 Data Aggregation & Visualization software module version 3.0 and the T3 Risk Analytics Engine software module version 3.0) cleared under K163065

4.0 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 in real-time. 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

This release of the T3 Platform Software contains the following software module changes:

T3 Risk Analytics Engine software module version 5.0

1) IVCO2 Index™. The subject device is a modification of the T3 Platform software clearance under K163065 that expands the Indications for Use for inadequate ventilation of carbon dioxide index (IVCO2 Index™). The IVCO2 Index™ calculates a patient status index. This is a measure of the likelihood that an arterial blood gas measurement of carbon dioxide would indicate a partial pressure greater than 50 mmHg.

2) Minor changes to maintain the performance of the IDO2 Index™ when external factors exist. Minor changes to the IDO2 Index™ have been made to maintain the specified performance of the IDO2 Index™ when variations in external factors exist. Specifically, these included changes in the initialization routine to ensure that the algorithm converges to stable behavior within the required time window, and changes in the artifact rejection logic of noninvasive blood pressure measurements to ensure that these measurements are not ignored when only minimum data is available thus providing required minimum data performance.

T3 Data Aggregation & Visualization software module version 3.3

1) *Index Displayed on Census View.* IDO2 Index™ and the IVCO2 Index™ are not displayed on the Census View and the requirement was removed.

2) *Blackout*. To mitigate potential misuse of active patient monitoring with Persistent Displays in the ICU, the IDO2 Index™ and the IVCO2 Index™ are blacked out in the near-real-time, a warning label is placed above the Index, and a user is prompted to acknowledge warnings when selecting an Index to be graphed.

3) *Measure synonyms.* Certain measures, while not identical to each other, are nevertheless closely related and can be thought of as "synonyms" for each other. For example, "Temp" (Generic Temperature), "Tairwy" (Airway Temperature), "Tesoph" (Esophogeal Temperature), and "Ttymp" (Tympanic Temperature) are all measures of the patient's temperature. In this example, the measure synonym feature would allow T3 Data Aggregation & Visualization software module to continuously report a value for "Temperature" based on whatever values were being received for Temp, Tairwy, Tesoph and/or Ttymp. The raw (source) variables continue to be available to be seen or graphed. In addition, this feature includes an "explain" function that allows the clinician to examine measure synonyms to see the source of the displayed data value at each moment in time.

4) *Respiratory View.* T3 Data Aggregation & Visualization software module now includes a screen that displays measures and laboratory results related to the patient's respiratory system. This predefined arrangement, accessed by clicking on the "Respiratory" tab beside the previously released "Hemodynamic" view, saves the clinician the time and effort of graphing these laboratory data and measures in order to understand the status and trend of the patient's respiratory system. The respiratory view includes Smart Visualization Groups that show measures and labs related to respiratory rate, ventilation pressure, respiratory volume, oxygenation, and ventilation.

5) *Placement of IDO2 at the top of the Patient View.* In the T3 Data Aggregation & Visualization software module, the display canvas for IDO2 Index™ has been moved to the top of the Patient View.

6) *Current measure value is shown on the graph instead of the legend.* When the user positions the mouse cursor in the central graph area, T3 Data Aggregation & Visualization software module displays the value of all graphed measures for the time corresponding to the cursor location. Previous releases of T3 Data Aggregation & Visualization software module displayed this information on the legend (the label for each measure or laboratory result that is shown to the left of the graph area). This release of T3 Data Aggregation & Visualization software module instead shows the value beside a light vertical line that is drawn at the mouse cursor position. This moves the information closer to the user's focus of attention (the mouse cursor).

7) *Ability to receive and merge multiple data interfaces of the same type.* T3 Data Aggregation & Visualization software module currently receives three types of data interfaces: patient registration (ADT), laboratory results, and physiometric data. This release allows T3 Data Aggregation & Visualization software module to receive and merge data interfaces of the same type coming from two or more sources. For example, a physiometric data interface for beds from a particular floor of the hospital can now be merged with a separate physiometric data interface with beds from a different floor or unit. This feature allows clinicians to view collections of beds that correspond to patient care trajectories such as the operating room and recovery unit, or intensive care and step-down unit.

8) *Ability to receive data through SQL relational database query.* Previous releases of T3 Data Aggregation & Visualization software module received data exclusively through HL7-based data interfaces. However, depending on a hospital's IT infrastructure, data from peripheral devices like ventilators may be sent to the hospital electronic medical record but not broadcast through an HL7 data interface. This release of T3 Data Aggregation & Visualization software module retains its HL7 functionality, but also supplements it with the ability to simultaneously receive other data through periodic SQL relational database queries. (SQL, structured query language, is the ANSI standard language for relational database management systems). For example, T3 Data Aggregation & Visualization software module can query a hospital database periodically to read validated ventilator values that are not otherwise transmitted through HL7 data interfaces, while simultaneously receiving device and lab data through HL7.

9) *Support for an expanded number of beds.* This release of T3 Platform software permits an instance of T3 web server to support up to 128 intensive-care beds. Previously an instance of T3 web server could only support 30 intensive-care beds. The server-side hardware requirements have been modified to request additional hard disk space for T3 web server to support more beds.

5.0 Indications for Use

The T3 Platform™ software features the T3 Data Aggregation & Visualization software module version 3.3 and the T3 Risk Analytics Engine software module version 5.0.

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:

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- Heart rate variability
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- Pulse pressure variation
- Pulse Rate
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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 3.3 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.

6.0 Comparison of Technological Characteristics with the Predicate Device

The subject and predicate T3 Platform software are web-based and designed to acquire data from the network source and display the information remotely for clinicians to use in the care of their adult, pediatric and neonatal patients. For certain indicated patients, the IDO2 Index™ is displayed alongside the acquired data.

The subject and predicate T3 Platform software products differ in that for another set of indicated patients, the IVCO2 Index™ is displayed alongside the acquired data. The IVCO2 Index™ included in the T3 Platform software (subject device) is indicated for use with ventilated patients aged 29 days to twelve years weighing 2 kg or more under intensive care.

The subject device contains the labeling changes and new product features. The subject device has labeling and new features that include the IVCO2 Index™ along with the cleared IDO2 Index™, changes to the IDO2 Index™ that have been made to maintain the specified performance of the IDO2 Index™ when variations in external factors exist, the IDO2 Index™ and the IVCO2 Index™ are blacked out in the near-real-time, closely related measures are treated as "synonyms" for reporting, the addition of a respiratory view, the ability to receive and merge multiple data interfaces of the same type, the ability to receive data through SQL relational database query, and a server support for up to 128 intensive-care beds.

7.0 Performance Data

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 the safety and effectiveness of the subject T3 Platform software (subject device) is comparable to that of the predicate T3 Platform software (target device).

In addition, validation study results using clinical data gathered in the intended patient population demonstrate the IVCO2 Index™ included in the subject device were validated with the changes in the patient's physical status. To support the use of the IVCO2 Index™ in the indicated patient population, the enclosed 510(k) application includes, in part, performance test results using clinical data, covering the indicated patient age range.

Specifically, the IVCO2 index was retrospectively computed on data acquired from 951 patients. The ability of the index to correctly discriminate the physiologic state of inadequate ventilation of carbon dioxide though its whole range, while remaining robust against different data availability was validated by using arterial blood gasses as gold standard.

8.0 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.