DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 26, 2017

Etiometry, Inc.
% Richard Galgon
Independent Consulting Associate
Quintiles
5846 Cobblestone Lane
Waunakee, Wisconsin 53597

Re: K163065
Trade/Device Name: T3 Software (Version 3.0)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, PLB
Dated: April 24, 2017
Received: April 26, 2017

Dear Richard Galgon:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163065

Device Name
T3 Software (Version 3.0)

Indications for Use *(Describe)*

The T3 Software is intended for the recording and display of multiple physiological parameters of adult, pediatric and neonatal patients from supported bedside devices. T3 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. T3 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.

T3 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)

It can also display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid.

T3 includes a Patient Risk Analytics Engine that calculates an index (the Inadequate Oxygen Delivery Index) that is indicated for use by health care professionals with postsurgical patients aged zero days to twelve years weighing 2 kg or more under intensive care. The Inadequate Oxygen Delivery Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by T3. When the index is elevated, it means that there is increased risk of inadequate oxygen delivery and attention should be brought to the patient. The 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:
T3 Software is not an active patient monitoring system. It is intended to supplement and not replace any part of the hospital's device monitoring. Do not rely on the T3 Software Solution as the sole source of patient status information.

The scale for the Inadequate Oxygen Delivery Index (IDO2) is the opposite of the scale for oxygen saturation measurements such as those provided by pulse oximetry. A high value for IDO2 indicates increased risk of inadequate oxygen delivery. A low value indicates reduced risk or normality.

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.

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510(k) Summary

I. 510(k) Submitter

Company Name and Address:

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Date Prepared: May 18, 2017

II. Device

Device Trade Name: T3 Software (Version 3.0)

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

Product Code: MWI; monitor, physiological, patient (without arrhythmia detection or alarms). Secondary code is PLB: Automated calculation of a summary index (or indices) based on several individual measured vital sign inputs.

III. Predicate Device

T3 Software (Version 2.0) cleared under K152258

IV. 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

The subject device is a modification of the T3 Software that expands the Indications for Use for the Inadequate Oxygen Delivery Index (IDO2) from patients aged 0 – 28 days to patients aged zero days to twelve years. The IDO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by T3. This index provides an interpretation of how different the patient's physiologic measures are from normality.

In addition to the expansion in the Indications of Use for the IDO2 Index, T3 release 3.0 contains the following changes:

1) In previous T3 versions, the Inadequate Oxygen Delivery Index is documented as having the following limitation.

   The index will not be displayed if the following minimum measurements are not available:
   - *a. Heart rate from ECG or pulse at a minimum of once every 30 seconds*
   - *b. SpO2 from pulse oximetry at a minimum of once every 30 seconds*
   - c. *Blood Pressure (mean/diastolic/systolic) at a minimum of once every 10 minutes*

   This limitation has been changed to the following:

   The index will not be displayed if the following minimum measurements are not available:
   - *a. Heart rate from ECG or pulse at a minimum of <u>once every 60 seconds</u>*
   - *b. SpO2 from pulse oximetry at a minimum of <u>once every 10 minutes</u>*
   - *c. Blood Pressure (mean/diastolic/systolic) at a minimum of once every 10 minutes*

   The minimum requirement for Heart Rate data has changed from 30 seconds to 60 seconds, and the minimum requirement for SpO2 has changed from 30 seconds to 10 minutes.

2) In previous T3 versions, the software model used to calculate IDO2 had age independent parameters and did not include a number of potentially useful model relationships. In the updated model, parameters are now dependent on patient age. Also, new model states and relationships have been implemented to improve the performance.

3) In previous T3 versions, the calibration logic for IDO2 utilized the probability distribution of patient states to determine whether or not to display a given IDO2

value. The new calibration logic is simply time based, waiting 5 minutes to display IDO2 values for a new patient. In addition, if the algorithm is re-initialized for any reason, it will undergo an additional 5 minutes of calibration after the re-initialization.

4) The IDO2 labeling contains a list of required and optional algorithm inputs. One required input is SpO2. Previous releases of T3 accepted SpO2 captured by the patient monitor and reported with any of three different labels: "SpO2" (defined as "SpO2 from pulse oximeter"), "SpO2_l" (defined as "arterial oxygen saturation left"), and "SpO2_r" (defined as "arterial oxygen saturation right"). This release of T3 adds SpO2 as reported with two other labels: "SpO2_pr" (defined as "pre-ductal SpO2") and "SpO2_po" (defined as "post-ductal SpO2").

5) T3 version 3.0 also includes the following User Interface changes:

    a. A new user interface mode that displays the data originating from a single bed location, even as new patients are transferred into that location. The benefit of this change is that the T3 user is never auto-logged off due to inactivity. Instead, T3 displays either the view of the patient data or a dialog stating that no data is being received for the bed. The mode is suitable for a bedside display, and saves clinicians the time and effort of logging in and navigating to that patient's data each time they want to use T3. To mitigate possible clinician confusion about which patient the data is for, T3 only displays data for one patient at a time – the current patient. Furthermore, the patient's name, medical record number and date of birth are displayed on the screen.

    b. Views: These are predefined arrangements of labs and measures. Views are accessed through a tabbed display. The first instance of the View functionality is the Hemodynamic View, which presents information about the patient's hemodynamic system. Views save clinicians the time and effort to drag meaningful labs and measures to the central graph area in order to display them.

    c. Smart Visualization Groups: These are collections of measures and laboratory results that are graphed together as a single unit. T3 is able to insert shading, vertical lines and other visual cues to emphasize relationships in the data. For example, in the Blood Pressure group, the area between systolic and diastolic pressure is shaded. The shading represents "pulse pressure," a standard measure of the force the heart generates each time it contracts. The shading allows the clinician to see increases or decreases in pulse pressure, in addition to the systolic and diastolic blood pressure values from which pulse pressure is calculated.

    d. When T3 displays a measure it inserts the starting and ending values for the period of time being graphed on the left and right edges of the canvas. It inserts the maximum and minimum values for the measure in circles at the point in time when they occur. If two or more of these values would overlap

on the graph, T3 omits all but one of them for clarity. Likewise, if one of these values would obscure the graphic icon for a laboratory result, T3 omits it so the laboratory result is shown.

e. Night Mode. There are now application-wide configuration settings that specify when "night time" starts and ends. For example, night time can be defined to start at 7PM and end at 7AM - or whatever times are desired. When T3 runs "at night," the application recognizes that it is night based on the system clock, and automatically uses a dark background. This reduces the amount of ambient light that the T3 monitor emits. When it runs during the day, T3 similarly recognizes that it is day and automatically uses a light background. It is possible for individual users to manually override the night mode function. On the patient view screen, T3 adds buttons that let the user manually control night mode. There is a sunshine button that lightens the background, and a moon button that darkens the background. A lock button locks in the user's selection of day or night.

f. If T3 receives data for a patient measure whose unit of measure is different from what was previously received for that patient and measure, it now displays a temporary warning banner at the top of the display that is automatically dismissed after ten seconds. Previously, T3 displayed the warning, but required the user to dismiss it by clicking on it. In many situations, needing to click to dismiss the warning was inconvenient or impractical. An example of this functionality is if T3 is receiving mean airway pressure for a patient. The monitor may report values in "millibars" then switch to "cmH2O." Both are commonly accepted ways of measuring airway pressure. In this case, the warning will say "Measure **mnAWp** has inconsistent unit codes. T3 is expecting units of **mbar**, but received data points with units of **cmH2O**. Those data points will not be displayed."

g. The dialog showing additional details for a lab value is now invoked by clicking anywhere on the lab icon. Previously it was invoked by hovering the mouse cursor over the exact data point for the lab value. The new functionality is more forgiving if the mouse cursor is slightly misplaced, and is less susceptible to displaying unwanted tooltips when the user moves the mouse cursor around the screen.

6) Typically, a clinician enters the patient's medical record number (MRN) into the bedside monitor. The physio interface sent to T3 from that monitor then includes the MRN and bed location along with the data values for the patient. T3 now supports an alternate workflow where the hospital's Admit, Discharge and Transfer (ADT) interface is used as the definitive source of patient identity and location information. The physio interface contains bed location along with the data values for the patient, but T3 derives the MRN by matching the bed location sent in the physio interface with the bed location / MRN pairing sent in the ADT interface. In order to recover from a situation where an ADT message is not delivered to T3 for some reason, or T3

processes it incorrectly, there is also a user interface in T3 that allows an administrator to explicitly specify the MRN for the patient occupying a bed location. This has the same effect as an ADT message associating a patient with a bed location.

7) T3 can now send an informational email to one or more configured email addresses when it detects that data is being received from a bed location without an associated patient medical record number, or when it detects that data is simultaneously being received from multiple bed locations with the same associated MRN. The recipient of the email can then investigate and correct the problem. The email does not contain protected health information; instead it specifies the bed locations where the issue occurs.

8) The T3 labeling lists a series of clinical calculations that can be configured upon clinician demand. These clinical calculations are simple algebraic formulas that accept raw parameters and output a single result. An example is Pulse Width which is equal to Systolic blood pressure minus Diastolic blood pressure. This release of T3 adds the following calculations to the list that may be requested by clinicians:

Label	Name	Formula
P/F	P/F Ratio	PaO2 / FiO2
S/F	S/F Ratio	SpO2 / FiO2
OI	Oxygenation Index	(FiO2 * Mean Airway Pressure * 100) / PaO2
OSI	Oxygen Saturation Index	(FiO2 * Mean Airway Pressure * 100) / SpO2

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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
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The scale for the Inadequate Oxygen Delivery Index (IDO2) is the opposite of the scale for oxygen saturation measurements such as those provided by pulse oximetry. A **high** value for IDO2 indicates **increased risk** of inadequate oxygen delivery. A low value indicates reduced risk or normality.

V. Comparison of Technological Characteristics with the Predicate Device

The subject and predicate T3 Software systems 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, a derived index, the Inadequate Oxygen Delivery Index, is displayed alongside the acquired data.

The subject and predicate T3 software products differ in that the IDO2 included in Version 2.0 of the T3 Software (predicate device) is indicated for use with neo-natal patients (0-28 days). The IDO2 included in Version 3.0 of the T3 software (subject device) is indicated for use with patients aged zero days to twelve years.

Version 3.0 of the T3 software also contains the labeling changes and new product features listed above in **Section IV Device Description**.

VI. Performance Data

Software verification and validation testing was 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 software product (Ver. 3.0) is comparable to that of the predicate T3 software products (Ver. 2.0.1).

In addition, validation study results using clinical data gathered in the intended patient population demonstrate the IDO2 Index included in the subject device correlates with changes in the patient's physical status. To support the use of the IDO2 index in the expanded patient population, the enclosed 510(k) application includes, in part, performance test results using clinical data from 1504 patients, covering the expanded patient age range.

VII. Conclusions

Substantial equivalence of the T3 Software is demonstrated through performance testing. The T3 Software has equivalent design, features and functionality as the predicate T3 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.