DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2016

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

Re: K152258
Trade/Device Name: T3 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: February 19, 2016
Received: February 24, 2016

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.

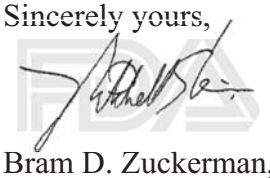
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 yours,



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)*
K152258

Device Name
T3 Software Version 2.0.1

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 post-surgical neonatal patients 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.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

WARNING: 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.

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)

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.

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510(k) Summary

510(k) Number K152258

I. 510(k) Submitter

Company Name and Address:

Etiometry, Inc.
119 Braintree Street
Boston, MA 02134

Company Contact: Dimitar Baronov, PhD Chief Technology Officer
Phone: 857.366.9333 ext. 2005
E-mail: baronov@etiometry.com

Date Prepared: March 30, 2016

II. Device

Device Trade Name: T3 Software (Version 2.0.1)

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

III. Predicate Device

1. T3 Software (Version 1.9) cleared under K142732 and K151715.
2. Visensia cleared under K081140 and K110953.

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 includes Risk Analytics Engine that computes an Inadequate Oxygen Delivery Index (IDO2). 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.

Indications for Use

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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 patients. The subject T3 software is designed for future scalability and requires a second server where the Risk Analytics Engine runs.

The subject T3 and predicate Visensia software are designed to acquire data from the network source and display the information remotely for clinicians to use in the care of their patients, alongside a derived index. The subject T3 software differs from the predicate Visensia device in requiring a more powerful CPU, more RAM, and a bigger hard drive. Also the subject T3 software runs on Red Hat Enterprise Linux while the predicate Visensia device runs on Microsoft Windows

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. 2.0.1) is comparable to that of the predicate T3 software products (Ver. 1.9) and the Visensia device.

Additionally, 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, as does the Visensia Index.

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 devices.