



Food and Drug Administration  
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October 29, 2015

Etiometry, Inc.  
% Richard Galgon  
Independent Consulting Associate  
Quintiles  
1708 Suwannee Circle  
Waunakee, Wisconsin 53597

Re: K151715

Trade/Device Name: T3 Software Version 1.9  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardio-tachometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI  
Dated: September 16, 2015  
Received: September 25, 2015

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored background of the FDA logo.

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) **K151715**  
To be assigned

Device Name  
T3 Software Version 1.9

#### 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.

**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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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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

### 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: June 24, 2015

### II. Device

Device Trade Name: T3 Software (Version 1.9.1)

Device Common/Usual Name: Data Management Software (without alarms)

Classification Name: Cardiac monitor (including cardiometer and rate alarm)

Classification Number: 870.2300

Regulatory Class: II

Product Code: MWI; monitor, physiological, patient (without arrhythmia detection or alarms)

### III. Predicate Device

T3 Software (Version 1.8), cleared under K142732.

#### 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 T3 Software is intended for the display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. T3 is not intended for alarm notification, nor is it intended to control any of the independent bedside devices to which it is connected

The T3 software can display user-defined, derived measures. These measures include the percentage of time within a time period that a particular variable is above or below a threshold. The user can configure the time period, threshold, and label of the resulting derived measure for ease of use considerations, only.

The 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.

T3 has a web architecture consisting of a user interface that runs in a browser, and a central web server. The T3 server, a set of cooperating web services written in Java, processes data as it is received, caches it in memory, and writes out copies of the data to a relational database and to the file system. In this manner, the data is available to the user interface to be visualized by the end user – a clinician.

Clinicians access the T3 user interface in a web browser. T3 runs in current browsers that support HTML5, Javascript and web sockets, such as Chrome, Firefox, Safari and Internet Explorer. The clinicians may be in the hospital, or may be outside the hospital accessing T3 over a Virtual Private Network (VPN). Clinicians use T3 in addition to the physiometric devices themselves and other information sources such as the electronic medical record to monitor the patient's condition.

## V. Indications for Use

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 CO<sub>2</sub>
- Heart rate
- Heart rate variability
- Intracranial pressure
- Left atrium pressure
- Oxygen saturation (intravascular, regional, SpO<sub>2</sub>)
- 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.

**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..

The T3 and predicate T3 Software Indications for Use are the same with respect to recording and remote display of medical device data from supported devices. The Indications for Use are also the same with respect to the user and use environment, hospital. The T3 and predicate T3 Indications for Use differ insofar as T3 can additionally display laboratory measurements including arterial and venous blood gases, complete blood count and lactic acid.

Neither T3 nor the predicate T3 Software is intended to replace any part of the hospital's device monitoring systems; and are also not intended to be used as the sole source of information in the care of the patient.

## **VI. Comparison of Technological Characteristics with the Predicate Device**

T3 has similar features and functionality as the predicate T3 Software system with the exception of the differences noted above. The 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 technological characteristics implemented in T3 software to achieve this interaction are similar to the predicate device as well.

## **VII. Performance Data**

Software verification and validation testing has been conducted for T3 Software and documentation has been provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005. T3 Software is considered a moderate level of concern since a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Since T3 Software is a software medical device, biocompatibility testing, electrical safety and electromagnetic compatibility (EMC) testing, sterilization and shelf-life information were not required.

Animal testing was not required.

Clinical testing was not required.

**VIII. 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 can be considered substantially equivalent.