K102507

JUN 13 2011

Abbreviated 510(k)

Summary of Safety and Effectiveness

1. General

A) Submitter Name and Address:

TZ Medical, Inc.
7272 SW Durham Rd, Suite #800
Portland, OR 97224

B) Contact Name and Phone Number:

John Lubisich
800-944-0187 or 503-639-0282

2. Device Identification

Trade name/Proprietary:	Aera CT TZ Medical MCOT ECG Monitor and Arrhythmia Detector
Common Name:	Arrhythmia Detector and Alarm
Classification Name:	Arrhythmia Detector and Alarm
Product Code:	DSI (21 CFR Part 870.1025)
Class:	Class II with Special Controls
Panel:	74 Circulatory System Devices

3. Predicate Devices

K072558	CardioNet ECG Monitor with Arrhythmia Detector Model CN1005
K100155	Biomedical Systems Inc. Monitor with Arrhythmia Detector Model TruVue

4. Indications for Use and Contraindications

Indications for Use:

The device is intended for use by individuals who are at risk of having cardiac disease and those that have intermittent symptoms indicative of cardiac disease and demonstrated a need to be monitored on a continuing basis. The ECG recordings can be uploaded to monitoring center in a variety of ways - transmitted via Cellular RF Modem, via RF, via TTL, or flash card to an FTP storage location or software package to be read by a healthcare professional.

Patients include, but at are not limited to, those requiring monitoring for a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACS, PSVT)

and ventricular ectopy, b) evaluation of bradyarrhthmias and intermittent bundle branch block including after cardiovascular surgery and myocardial infarction, and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

Patients with symptoms that may be due to cardiac arrhythmias. These may include, but are not limited to, symptoms such as a) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded, c) dyspnea (shortness of breath). Patients with palpitations with or without known arrhythmias to obtain correlation or arrhythmias with symptoms.

Patients who requiring monitoring of the effects of drugs to control ventricular rate in atrial arrhythmias (e.g. atrial fibrillation).

Patients recovery from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive central) to evaluate possible nocturnal arrhythmias.

Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or flutter.

Data from this device may be used by another device to analyze , measure or report QT interval . The device is not intended to sound any alarms for QT interval changes.

Contraindications:
Patients with potentially life-threatening arrhythmias who require inpatient monitoring.

Patients who the attending physician thinks should be hospitalized.

Note:
The Aera CT system does not provide interpretive or diagnostic statements. Interpretation and diagnosis is the responsibility of a trained healthcare professional or physician.

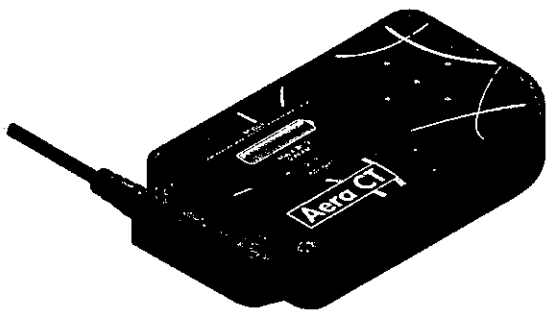
5. Device Description

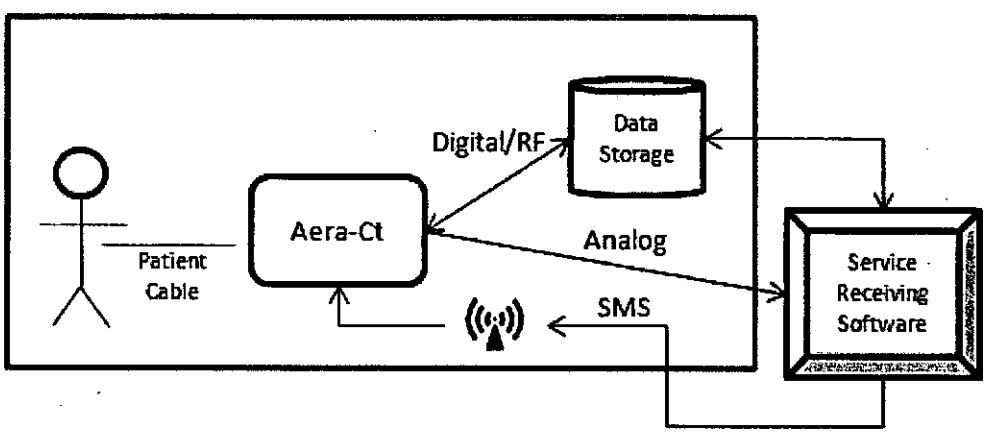
The Aera CT is an ECG Device with auto trigger capability using MCOT compliant wireless technology for monitoring ambulatory patients with non-life threatening conditions.

The device is composed of patient (ECG) leads, monitor, and charging wall board adapter.

A sensor captures the ECG signal from the patient's body and transmits the signal to the small (hand sized) monitor where data is stored and analyzed by automated arrhythmia analysis algorithms. When events are detected by the arrhythmia analysis algorithm or when the event

processing event key is depressed, the data is transmitted by RF to a data storage location monitored by receiving center. The transmission may occur via Cellular RF modem, RF, or TTL via a landline telephone. The data is received and reviewed by the appropriately trained healthcare professionals or technicians. Request for additional data can be sent to MCT device via SMS text formatted message that will originate from the receiving software.





6. Comparison to Predicate Devices

There is no primary technological difference between TZ Medical's Aera CT device and the predicate devices (K072558) CardioNet CN1005S and (K100155) Biomedical Systems Inc TruVue System.

The following chart describes further comparison.

Characteristics	Subject Device Aera CT TZ Medical	Predicate Device 1 CN1005 CardioNet (K072558)	Predicate Device 2 TruVue Biomedical Systems (K100155)
Patient population	Patients requiring cardiac monitoring who are ambulatory and without life-threatening arrhythmia conditions	Same	Same
Environment for Intended Use	Ambulatory, Outpatient	Same	Same
Basic Technology	Analog Front end, MCU running detection Algorithm, Flash Storage, Modem for transmission	Same	Same
System communication / Transmission	RF Modem, Cellular RF Modem, Transtelephonic Transmissions	Cellular RF Modem, RF Modem to Base, Transtelephonic Transmission via landline	Cellular RF Modem, Transtelephonic Transmission
Ambulatory ECG performance standards	EC 38 compliant	Same	Same
Algorithm	Proprietary / Device side	Proprietary / Device Side	Proprietary /Server Side
Indicators / Alarms	NONE	NONE	NONE

Element 807.92 (6)(b)(1)

The TZ Medical has developed tests using the same requirements that CardioNet (K072558) and (k100155) have used and stated that their devices comply with in their respective 510k submission. The TZ Medical device and the two predicated devices are tested to and comply with all applicable tests and requirements in the relevant standards as stated in this submission.

Element 807.92 (6)(b)(2)

TZ Medical will compile and analyze clinical test data at a trial site prior to use. Results of data will be used as part of the validation and verification data submitted with the design file. Clinical test will be conducted at facilities that are familiar with predicate devices and will submit reports verifying substantial equivalence to competitive products and on performance to specifications.

7. Substantial Equivalence Conclusion

TZ Medical's Aera CT, monitor with arrhythmia detection has the same intended use, similar operating principles and technological characteristics as the predicate devices. Based on the descriptive information and the performance testing and validation, the Aera CT is as safe and effective as the predicate devices. Therefore, the Aera CT is substantially equivalent to the predicate devices.

8. Referenced Standards

FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

(IEC) 60601-1-1:1998 Medical Electrical Equipment –Part 1 General Requirements for Safety

(IEC) 60601-1-2:2001,Second edition Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility

(AAMI) EC 38:2007 Ambulatory Electrocardiographs

(ANSI/ AAMI) EC 57:1998 Testing & reporting performance results of cardiac and ST-segment measurement algorithms

IEC 60601-1-4 + A1:1999 : General Requirements for safety 4. Collateral Standard: Programmable Electrical Medical Systems

IEC 14971-2007: Application of risk management to medical devices

ISO 15223-1:2007 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

Note: AAMI EC 11 and EC 13 Do not apply to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

TZ Medical Inc.
c/o Mr. John Lubisich
VP of Operations
7272 SW Durham Road, Suite #800
Portland, OR 97224

JUN 13 2011

Re: K102507
Device Name: Aera CT
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient physiological monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (Two)
Product Codes: DSI
Dated: June 7, 201
Received: June 9, 2010

Dear Mr. Lubisich:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102507

Device Name: Aera CT

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c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

(Continued on Second page)

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BZuckerman 6/13/2011

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102507

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These may include, but are not limited to, symptoms such as
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for B Zuckerman

(Division Sign-Off) 6/13/2011
Division of Cardiovascular Devices
510(k) Number K102507