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 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 bradyarrhythmias 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.
### Table

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

**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


(AAMI) EC 38:2007 Ambulatory Electrocardiographs

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


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.
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” (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 Small Manufacturers, International and Consumer Assistance at its toll-free number
(800) 638-2041 or (301) 796-7100 or at its Internet address

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

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 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 bradyarrhythmias 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.

(Continued on Second page)

Prescription Use x AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off) Division of Cardiovascular Devices

510(k) Number K102507
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,
b) 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.

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