



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

January 27, 2016

Edan Instruments, Inc.  
% Mr. Doug Worth  
Sr. Dir. US RA/QA  
Edan Medical  
1200 Crossman Ave., Suite 200  
Sunnyvale, California 94086

Re: K151787

Trade/Device Name: Holter System, models SE-2003 and SE-2012  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II  
Product Code: DQK, MWJ  
Dated: December 29, 2015  
Received: January 4, 2016

Dear Mr. Worth:

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

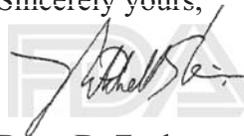
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 watermark 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

## Indications for Use

510(k) Number (if known)

K151787

Device Name

Holter System, models SE-2003 and SE-2012

Indications for Use (Describe)

The SE-2003/SE-2012 Holter System (including recorder and analysis software) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg.

It can be used for the following indications:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of patients for ST segment changes.
3. Evaluation of drug response in patients taking anti-arrhythmic medications.
4. Evaluation of patients with pacemakers.

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.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(K) Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

- 1. Submitter:** Edan Instruments, Inc.  
3/F - B, Nanshan Medical  
Equipments Park, Nanhai Rd 1019#,  
Shekou, Nanshan Shenzhen,  
518067 P.R. China  
Tel: +86(0755) 26858736  
Fax: +1 (408) 418-4059
- Contact person:** Queena Chen  
**Preparing date:** December 29, 2015
- 2. Device name and classification:** **Device Name:** Holter System, models SE-2003 and SE-2012  
**Classification Name/ Product code:**  
870.1425 Computer, Diagnostic, Programmable/DQK  
870.2800 Electrocardiograph, Ambulatory (Without Analysis)/MWJ  
**Regulatory Class:** Class II
- 3.Premarket Notification Class III Certification and Summary** Not applicable, the subject device is Class II.
- 4. Predicate Device(s):** 1) Mortara Instrument, Inc. H3+, K043010 (SE-2003)  
2) Mortara Instrument, Inc. H12+, K050896 (SE-2012)  
3) GE Healthcare, MARS Holter Analysis Workstation, K132437  
4) North East Monitoring, Inc. DR300 Holter Monitor, K142424  
5) CardioNet, Inc. Model CIN 1006 - CardioNet ECG Monitor with Arrhythmia Detection, K093288
- 5. Reason for Submission** New Device.
- 6. Pre-Submission, IDE** Not applicable, there is no prior submission.
- 7. Device Description:** The Holter System, composed of a Holter recorder and Holter software, is designed to record and analyze continuous long-time (24-192 hours) ECG data. The Holter recorder

contains lead wires and removable SD flash card to record ECG signals. The Holter software is installed in generally used PC to analyze recorded ECG data from Holter recorder. Typical recording time of Holter recorder powered by one AAA size battery with removable SD flash card is more than 24 hours up to 192 hours. Recorders are carried around by patients with a set of electrodes arranged by certain rules on them which are connected to recorders by lead wires. Patients are requested to come back to medical treatment site after recording time. The ECG data recorded in Holter recorders will be transferred into PCs and then analyzed, displayed and edited with the Holter software. An analysis report may be finally generated. The introduction of the Holter recorder and Holter software is as follows:

- Holter recorder has two models, the SE-2003 and SE-2012 with the same performance such as sampling rate, analog-to-digital converter (ADC), filter and so on. The only two differences is the number of channels of ECG Waveform and the recording time: SE-2003 is a three channel ECG with 5 or 7 Electrodes cable, with a 192-hour recording capability, and SE-2012 is a twelve channel ECG with 10 Electrodes cable, with a 144-hour recording capability. Both Holter recorders have the following functions:
  - Digital Sampling Rate 128~1024 Hz
  - Frequency Response 0.05 ~60Hz
  - A/D Conversion 8, 12, 16, 18bit
  - Record Times of the SE-2003 are 24~192 hours, and SE-2012 are 24~144 hours 1.46 inch OLED

Holter software has the following functions:

- Supporting multi-channel beat detection
- Accurate classification of QRS morphology
- Supporting automatic detection of arrhythmia
- Supporting re-analysis
- Strips can be reviewed, edited and saved
- Supporting full disclosure
- Analysis functions including Template, Events, Atrial Fibrillation/ Atrial Flutter (AFib/AFlut), Strips, ST

analysis, Pacing analysis, Heart Rate Variability (HRV) analysis, Heart Rate Turbulence (HRT) analysis, Obstructive Sleep Apnea (OSA) analysis, QT analysis, The Alternans of T Wave (TWA) analysis, Waterfall analysis, Ventricular Late Potential (VLP) analysis and Vector ECG (VCG) analysis.

- Supporting creating or modifying scenarios or function pages

### **8. Intended Use:**

The SE-2003/SE-2012 Holter System (including recorder and analysis software) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg.

It can be used for the following indications:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of patients for ST segment changes.
3. Evaluation of drug response in patients taking anti-arrhythmic medications.
4. Evaluation of patients with pacemakers.

### **9. Predicate Device Comparison**

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters items, detailed comparison can be found in the following tables.

**Table 1: Comparison to Predicate Device(s) between SE-2003 and H3+**

<b>Item</b>	<b>SE-2003 (Edan Instruments, Inc)</b>	<b>H3+ (Mortara Instrument, Inc)</b>	<b>Comparison Result</b>
510(k) Number	Current Submission	K043010	—
Indications for Use	The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG.	The H3+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory	Different

Item	SE-2003 (Edan Instruments, Inc)	H3+ (Mortara Instrument, Inc)	Comparison Result
	<p>The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg. It is mainly used for (but not limited to) the following indications:</p> <ul style="list-style-type: none"> <li>● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of patients for ST segment changes.</li> <li>● Evaluation of drug response in patients taking anti-arrhythmic medications.</li> <li>● Evaluation of patients with pacemakers.</li> </ul>	<p>(Holter) monitoring of 24 hours. The Mortara Holter Recorder H3+ is not a life-supporting device. It is diagnostic tool intended to acquire, record and store ECG data of patients requiring ambulatory (Holter) monitoring of 24 or 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:</p> <ul style="list-style-type: none"> <li>● Evaluation of adult patients with symptoms suggesting arrhythmia</li> <li>● Evaluation of adult patients with pacemakers</li> <li>● Reporting of time domain heart rate variability</li> <li>● Evaluation of patients response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)</li> <li>● Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients</li> <li>● Clinical and epidemiological research studies</li> <li>● Infant patient evaluation is limited to QRS detection only</li> </ul>	
Energy	A single AAA alkaline	A single AAA alkaline battery	Same

<b>Item</b>	<b>SE-2003 (Edan Instruments, Inc)</b>	<b>H3+ (Mortara Instrument, Inc)</b>	<b>Comparison Result</b>
used and/or delivered	battery		
Channels	1,2,3-Channel	2,3-Channel	Different
Leads	Channel 1, Channel 2, Channel 3	Channel 1, Channel 2, Channel 3	Same
Physical Design	Length: 76 mm Width: 49 mm Thick: 16 mm Weight: 50 g	Length: 64 mm Width: 25 mm Thick: 19 mm Weight: 28 g	Different
Digital Sampling Rate	128~1024 Hz	180 Hz	Different
A/D Conversion	8, 12, 16, 18 bit	12 bit	Different
Frequency Response	0.05 Hz ~60 Hz	0.05 Hz ~60 Hz	Same
Input impedance	≥20 MΩ	≥47 MΩ	Different
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47	Same
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Same
Record Times	24~192 hours	24~48 hours	Different

**Table 2: Comparison to Predicate Device(s) between SE-2012 and H12+**

<b>Item</b>	<b>SE-2012 (Edan Instruments, Inc)</b>	<b>H12+ (Mortara Instrument, Inc)</b>	<b>Remark</b>
510(k) Number	Current Submission	K050896	—
Indications for Use	The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained	The H12+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of up to 48 hours. Such monitoring is	Different

Item	SE-2012 (Edan Instruments, Inc)	H12+ (Mortara Instrument, Inc)	Remark
	<p>personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg. It is mainly used for (but not limited to) the following indications:</p> <ul style="list-style-type: none"> <li>● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of patients for ST segment changes.</li> <li>● Evaluation of drug response in patients taking anti-arrhythmic medications.</li> <li>● Evaluation of patients with pacemakers.</li> </ul>	<p>most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:</p> <ul style="list-style-type: none"> <li>● Evaluation of adult patients with symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of adult patients for ST segment changes</li> <li>● Evaluation of adult patients with pacemakers</li> <li>● Reporting of time domain heart rate variability</li> <li>● Evaluation of a patients response after resuming occupational or recreational activities (e.g., after MI. or cardiac surgery.)</li> <li>● Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients</li> <li>● Clinical and epidemiological research studies</li> <li>● Infant patient evaluation is limited to QRS detection only</li> </ul>	
Energy used and/or delivered	A single AAA alkaline battery	A single AA alkaline battery	Different
Channels	12 Channel	12 Channel	Same
Leads	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Same
Physical	Length:76 mm	Length :64 mm	Different

Item	SE-2012 (Edan Instruments, Inc)	H12+ (Mortara Instrument, Inc)	Remark
Design	Width:49 mm Thick:16 mm Weight: 50 g	Width:91 mm Thick:25 mm Weight: 125 g	
Digital Sampling Rate	128~1024 Hz	180 Hz	Different
A/D Conversion	8, 12, 16, 18 bit	20 bit	Different
Frequency Response	0.05 Hz ~60 Hz	0.05 Hz ~60 Hz	Same
Input impedance	≥20 MΩ	≥47 MΩ	Different
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47	Same
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Same
Record Times	24~144 hours	24~48 hours	Different

**Table 3: Comparison to Predicate Device(s) between Holter analysis software and the MARS**

Item	Holter Analysis Software (Edan Instruments, Inc)	MARS (GE Healthcare)	Remark
510(k) Number	Current Submission	K132437	—
Indications for Use	The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients	MARS Holter Analysis Workstation is designed for acquisition, analysis, edit, review, report and storage of ambulatory EGG and multi-parameter data. Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded EGG data. The MARS Holter Analysis	Different

Item	Holter Analysis Software (Edan Instruments, Inc)	MARS (GE Healthcare)	Remark
	<p>including infants weighing less than 10 kg. It is mainly used for (but not limited to) the following indications:</p> <ul style="list-style-type: none"> <li>● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of patients for ST segment changes.</li> <li>● Evaluation of drug response in patients taking anti-arrhythmic medications.</li> <li>● Evaluation of patients with pacemakers.</li> </ul>	<p>Workstation is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric (greater than 10Kg) human patients. The MARS Holter Analysis Workstation provides the user arrhythmia studies and Holter analysis capabilities. Data acquired may be used for the following indications:</p> <ul style="list-style-type: none"> <li>● Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances</li> <li>● Evaluation of symptoms that may be due to myocardial ischemia</li> <li>● Detection of EGG events that alter prognosis in certain forms of heart disease</li> <li>● Detection and analysis of pacemaker function and failure</li> <li>● Determination of cardiac response to lifestyle</li> <li>● Evaluation of therapeutic interventions</li> <li>● Investigations in epidemiology and clinical trials</li> </ul>	
Review Modes	Strip review, Template review, Event review, Trend reviewer, Tabular and Page review	Strip review, Template review, Event review, Trend reviewer, and Page review	Different
Trend Graphs	HR, RR, ST, SVE, VE,	HR, RR, ST, SVE, VE	Different

Item	Holter Analysis Software (Edan Instruments, Inc)	MARS (GE Healthcare)	Remark
	SDNN		
Rhythm Analysis	Bradycardia, Tachycardia, Ventricular pairs, Ventricular tachycardia, Supraventricular pairs, Long R-R interval, Pause, Min/max heart rate, ST depression, ST elevation	Bradycardia, Tachycardia, Ventricular pairs, Ventricular tachycardia, Supraventricular pairs, Long R-R interval, Pause, Min/max heart rate, ST depression, ST elevation	Same
ST Segment Measurement	3/12 lead ST segment measurement, max ST depression, max ST elevation, 3/12 lead trends	3/12 lead ST segment measurement, max ST depression, max ST elevation, 3/12 lead trends	Same
Pacemaker Analysis	Atrial, ventricular and dual pacemaker detection; capture failure, Output failure, undersensing	Atrial, ventricular and dual pacemaker detection; capture failure, Output failure, undersensing	Same
QT analysis	QT Measurement	QT Measurement	Same
HRV analysis	Frequency domain analysis, Time domain analysis	Frequency domain analysis, Time domain analysis	Same

**Table 4: Comparison to Predicate Device(s) between Holter analysis software and the DR300**

Item	Holter Analysis Recorder & Software (Edan Instruments, Inc)	DR300 North East Monitoring	Remark
510(k) Number	Current Submission	K142424	—
Indications for Use	The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants	Holter Mode: Detection of Arrhythmias, Efficacy of Pharmacological Treatment and Pacemaker Evaluation.  Event Recorder: The event recorder module is a patient activated device designed to record and for diagnostic evaluation of transient symptoms (such as dizziness, palpitations, syncope, and chest pain). Once data is recorded, the	Different

Item	Holter Analysis Recorder & Software (Edan Instruments, Inc)	DR300 North East Monitoring	Remark
	weighing less than 10 kg. It is mainly used for (but not limited to) the following indications: <ul style="list-style-type: none"> <li>● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of patients for ST segment changes.</li> <li>● Evaluation of drug response in patients taking anti-arrhythmic medications.</li> <li>● Evaluation of patients with pacemakers.</li> </ul>	data is transmitted for evaluation.	
Target Population	for adult, pediatric patients including infants weighing less than 10 kg	patients (including infants weighing less than 10 kg) who may benefit from such monitoring	Same
Energy used and/or delivered	A single AAA alkaline battery	A single AA battery	Different
Physical Design	Length:76 mm Width:49 mm Thick:16 mm Weight: 50 g	Length 86mm (3.9in) Width: 60mm (2.4in) Thick: 20mm (0.8in) Weight: 70.9g (2.5 oz)	Different
Digital Sampling Rate	128~1024 Hz	180 Hz	Different
A/D Conversion	8, 12, 16, 18 bit	12 bit	Different
Frequency Response	0.05 Hz ~60 Hz	0.05 – 70 Hz	Different
Record Times	24~144 hours	336 hours	Different

**Table 5: Comparison to Predicate Device between Holter analysis software and CIN 1006 - CardioNet ECG Monitor**

Item	Holter Analysis Recorder & Software (Edan Instruments, Inc)	CIN 1006 - CardioNet ECG Monitor (CardioNet Inc.)	Remark
510(k) Number	Current Submission	K093288	—
Indications for Use	<p>The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg. It is mainly used for (but not limited to) the following indications:</p> <ul style="list-style-type: none"> <li>● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.</li> <li>● Evaluation of patients for ST segment changes.</li> <li>● Evaluation of drug response in patients taking anti-arrhythmic medications.</li> <li>● Evaluation of patients with pacemakers.</li> <li>● Evaluation of patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias.</li> </ul>	<p>The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:</p> <ol style="list-style-type: none"> <li>1. Patients who have a demonstrated need for cardiac Monitoring. These may include but are not limited to patients who require 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.</li> <li>2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of</li> </ol>	Different

Item	Holter Analysis Recorder & Software (Edan Instruments, Inc)	CIN 1006 - CardioNet ECG Monitor (CardioNet Inc.)	Remark
		<p>breath).</p> <p>3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.</p> <p>4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atria] fibrillation).</p> <p>5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring.</p> <p>6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias</p> <p>7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.</p> <p>8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter</p> <p>9. Patients who require</p>	

Item	Holter Analysis Recorder & Software (Edan Instruments, Inc)	CIN 1006 - CardioNet ECG Monitor (CardioNet Inc.)	Remark
		monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation). 10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.	
Record Times	24~144 hours	720 hours	Different

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

### **10. Performance Data:**

#### **Non-clinical data:**

The following performance data were provided in support of the substantial equivalence determination.

#### **Biocompatibility testing**

The biocompatibility evaluation for the Holter System were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

#### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Holter System, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 and the IEC 60601-1-2: 2007 standard for EMC.

#### **Bench Testing**

Bench testing was conducted per IEC 60601-2-47: 2012, and all the results show pass.

#### **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was

provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software will not directly result in serious injury or death to the patient or operator, and the software device is an accessory to a medical device that has a Moderate Level of Concern.

**Clinical data:** Not applicable.

### **Summary**

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

### **11. Conclusion**

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Holter System device should perform as intended in the specified use conditions, and all the data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject Holter System devices are substantially equivalent to the predicate devices.