



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

May 25, 2016

Vitasystems Gmbh
Michael Rothhaar
Director Corporate Quality
Markircher Str. 22
Mannheim, 68229 DE

Re: K153477

Trade/Device Name: Emma

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)

Regulatory Class: Class II

Product Code: DSI

Dated: April 11, 2016

Received: April 15, 2016

Dear Michael Rothhaar:

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

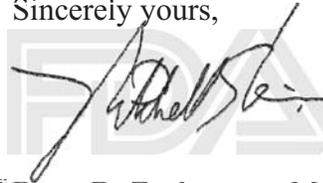
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 large, light gray 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)
K153477

Device Name
EMMa - Electronic Monitoring Management

Indications for Use (Describe)

The EMMa system is intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest non-lethal cardiac arrhythmia to support and possibly improve an ongoing treatment by the patient's physician. Data received from battery powered ambulatory monitoring devices, triggered by an arrhythmia detection algorithm or manually by the patient, are stored and forwarded to licensed physician for review.

Contraindications of Use:

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.

The software is not intended to be used to trigger emergency treatment or alert chains.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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EMMa

Electronic Monitoring Management

K153477

Submitter:

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Establishment

Registration Number:
Trade Name:

3005191294
EMMa Electronic Monitoring Management

Common Name:
Classification Name:

Cardiac Event Recorder Data Server
Detector and alarm, arrhythmia (per 21 CFR Section 870.1025, Product Code: DSI, DRG)

Date Prepared:

May 24, 2016

1. Legally Marketed Predicate Devices

K092947 DSI/DRG Telesentry, Model TS01, Scottcare Corporation

2. Indications & Intended Use

The EMMa (Electronic Monitoring Management) is a standalone software medical device. Connected with battery powered ambulatory ECG monitor devices, it acts as an arrhythmia detector and alarm device. EMMa is designed to receive data, to send configuration parameters to the devices and to enable qualified persons to assess and forward the received data.

Indication for use

The EMMa system is intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest non-lethal cardiac arrhythmia to support and possibly improve an ongoing treatment by the patient's physician. Data received from battery powered ambulatory monitoring devices, triggered by an arrhythmia detection algorithm or manually by the patient, are stored and forwarded to licensed physicians for review.

Contraindications of Use

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.

The software is not intended to be used to trigger emergency treatment or alert chains.

3. Product Description

EMMa (Electronic Monitoring Management) is the server part of a telemedical system to receive data from the ambulatory ECG monitors Kate Loop (Event Monitor) and Kate MCT (Mobile Cardiac Telemetry; similar to Loop but with additional functions like trend data and streaming).

Physiological data recorded by the ECG monitors are transmitted via their GSM module (cellular telephon network) to the server EMMa. The detection of arrhythmias and other cardiac conditions is done on the ECG monitoring device, not on the EMMa, and is not scope of this 510k.

EMMa is provided to be installed in a Telemonitoring Service Centre (TSC). ECG-technicians / Agents working there generate patient reports from physiological data with the aim to send the reports to the patients' physicians. No interpretation of data is performed by the server software. The generated reports support physicians in adapting the therapy. EMMa is not designed for and compatible with iOS and Android.

Data mapping is implemented by assignment of patient, physician and mobile ECG device in EMMa. The report technicians review ECG-strips and trend data and generate Daily Reports and End of Session Reports. These reports are sent to the assigned physician. A real time monitoring of patients is not feasible with this system.

Data transmissions are triggered by the mobile ECG monitors when abnormal events are detected. Declaration of remarkable events can be configured individually for each device via EMMa based on the patient's physician's recommendations.

Transmissions can also be triggered by a configured timer or manually by patients or agents.

The system supports the following events:

- Pause: short Sinoatrial arrest
- Afib: atrial fibrillation
- VES: ventricular extrasystoles

- VES Couplet: pairs of VES
- VES Triplet: three VES in a row
- Bigeminy: heart arrhythmia in which there is a continuous alternation of long and short heart beats
- SVES Single: single supraventricular extrasystoles
- Bradycardia: slow heart rate (under 60 bpm)
- Tachycardia: heart rate that exceeds the normal resting rate (over 100bpm):

4. Substantial Equivalence Discussion

	EMMa (subject device)	TeleSentry Model TS01	Comments
Premarket Notification Number	K153477	K092947	N/A
Classification	Arrhythmia detector and alarm	Arrhythmia detector and alarm	same
Product Code	DSI DRG	DSI DRG	same
Regulation Number	870.1025	870.1025	same
Class	II	II	same
Indication for Use	For diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest cardiac arrhythmia. The device continuously monitors and records the data, automatically records events triggered by an arrhythmia detection algorithm or manually by the patient, and automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician.	For diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest cardiac arrhythmia. The device continuously monitors and records the data, automatically records events triggered by an arrhythmia detection algorithm or manually by the patient, and automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician.	Same
Supported ECG devices	kate Loop + kate MCT	TeleSentry TS01	Similar, difference does not affect safety or performance
Supported ECG modes	Loop (Event Monitor) MCT (Mobile Cardiac Telemetry)	MCT	Difference does not affect safety or performance
Transmission method	GSM	Bluetooth/GSM/USB	Similar, difference does not affect safety or performance

	EMMa (subject device)	TeleSentry Model TS01	Comments
Device configuration via	GSM	Bluetooth + GSM	Similar, difference does not affect safety or performance
Device compatible to IOS or Android	NO	NO	same
WIFI	NO	NO	same
monitoring in real time / near real time	NO	NO	same
Patient management	Yes	Yes	same
Device management	Yes	Yes	same
Physician Management	Yes	Yes	same
ECG Viewer	Yes	Yes	same
ECG Live streaming	Yes	Yes	same
Trend-data analysis	Yes	Yes	same
Reports	End of Session, Daily Report, Event Report	End of Session, Daily Report, Event Report	same
Device configuration over the air	Yes	Yes	same
Display device status (Battery,GSM)	Yes	Yes	same
Leads-On/Leads-Off Event	Yes	Yes	same
Events	Pause, Afib, VES, VES Couplet, VES Triplet, Bigenimy, SVES Single, Bradycardia, Tachycardia	Tachycardia, Bradycardia, Pause, Afip	
ECG Channels	up to 3	3	same
Report Management	Creation and Management of reports inside the software	Creation of reports, no management	Similar, difference does not affect safety or performance
User Interface	Web Application	Windows Client	Similar, difference does not affect safety or performance
Audit trail	Yes	Yes	same

5. Non-Clinical Performance Data

Verification and validation activities established the safety and performance characteristics of the subject device with respect to the predicate device. The following performance data have been provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

- IEC 62304:2006, *Medical Device Software—Software life cycle processes*
- Software verification and validation testing was conducted and documentation provided as recommended by the FDA Guidance for Industry and FDA Staff, *Guidance for the Content of Software Contained in Medical Devices*. The software is determined as a “moderate” level of concern because a failure or latent flaw could lead to a minor injury to the patient through incorrect information or through the action of the care provider.

Other testing

- IEC 62366-1:2015, *Medical Devices Part 1—Application of usability engineering to medical devices*

EMMa Electronic Monitoring Management meets all the stated requirements and passed all the testing noted above.

6. Clinical Performance Data

Clinical data were not required to support the safety and effectiveness of the device EMMa.

7. Statement of Substantial Equivalence

Through the data and information presented, Vitasones GmbH considers EMMa as substantially equivalent to the previously mentioned predicate device. Any differences between the subject and predicate device have no significant influence on safety or effectiveness as established through performance testing. Therefore, EMMa raises no new issues of safety or effectiveness when compared to the predicate device.

Vitasones GmbH
Michael Rothhaar
Director Corporate Quality

Signature: Date: