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

March 29, 2015

Mega Electronics Ltd.
Taneli Vaaraniemi
Quality Engineer
Pioneerinkatu 6
Kuopio, 70800 FI

Re: K143032
Trade/Device Name: Emotion Faros ECG Mobile
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: February 6, 2015
Received: February 9, 2015

Dear Taneli Vaaraniemi,

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,

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

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)*
K143032

Device Name
eMotion Faros ECG Mobile

Indications for Use *(Describe)*
The eMotion Faros ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion Faros ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation.

Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters.

Indicated for adult patients who require clinical or non-clinical ECG monitoring in healthcare facility environment under supervision of a physician or prescript by the supervising physician to supplement data acquisition in home environment.

The eMotion Faros ECG Mobile does not provide any automatic analysis or diagnosis.

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
PRAStaff@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."

007 – 510(k) Summary

1. Submitter

Mega Electronics Ltd
Pioneerinkatu 6
KUOPIO
FI-70800
Finland
Phone: +358 17 581 7700
Fax: +358 17 580 0978
Contact: Taneli Vääräniemi, Quality Engineer
Email: taneli.vaaraniemi@megaemg.com

Registration Number: 1000425315

2. Date

March 25, 2015

3. Device Identification

Modified ECG Module Names:	a) eMotion Faros 90 b) eMotion Faros 180 c) eMotion Faros 360
Modified Health Gateway Interface	Virtual Clinic
Trade/Proprietary Name:	eMotion Faros ECG Mobile
Common/Usual Name:	Digital Ambulatory Monitor
Classification Name:	Transmitters And Receivers, Electrocardiograph, Telephone
Classification Regulation:	21 CFR 870.2920
Product Code:	DXH
Device Class:	Class II
Classification Panel:	Cardiovascular
Device Classification EU:	Class IIa
Medical Device Directive:	93/42EEC as a amended by 2007/47/EC

4. Substantial Equivalence, Predicate Device

eMotion ECG Mobile, 510(k) Number: K131699

Copyright© 2015, Mega Electronics Ltd

5. Device Description

The eMotion Faros ECG Mobile is a mobile device, PC and Internet based telemetry solution for the ambulant monitoring of the plug-in device data of chronic patients via a mobile network. Plug-in devices can be ECG devices, blood pressure monitors, weighing scales, etc. The device reads data from the plug-in device via a Bluetooth connection. The application in the mobile device sends the data to a server (Health Gateway) over mobile networks using the secured connection.

Data can be viewed from the Health Gateway server using the Virtual Clinic interface. Monitoring is performed using PC application that reads data from the server over the internet using the secured connection. ECG data is possible to record on eMotion Faros ECG sensors internal memory. Data from ECG sensors can be reviewed with eMotion EDF Viewer or uploaded via USB connection.

Data acquisition is performed using eMotion Faros ECG sensors and applicable plug-in devices. Faros ECG sensors are modified versions of eMotion ECG sensor which the FDA granted clearance on November 26, 2013 (K131699).

Intended Use

The eMotion Faros ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion Faros ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation.

Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters.

Indicated for adult patients who require clinical or non-clinical ECG monitoring in healthcare facility environment under supervision of a physician or prescript by the supervising physician to supplement data acquisition in home environment.

The eMotion Faros ECG Mobile does not provide any automatic analysis or diagnosis.

Copyright© 2015, Mega Electronics Ltd

6. Comparison of Technological Characteristics

The eMotion Faros ECG Mobile is modified device of the predicate device. With respect to intended use, technological characteristics and principles of operation are identical with Predicate device, eMotion ECG Mobile K131699. Comparison to Legally Marketed Device in section 009 provides more detailed information regarding the basis for the determination of substantial equivalence.

The technological characteristics and principles of operation of the modified device are the same as the predicate device.

	eMotion ECG sensor (K131699)	eMotion Faros 90 (modified device)	eMotion Faros 180 (modified device)	eMotion Faros 360 (modified device)
ECG Channel(s)	Online: 1-channel	Offline: 1-channel	Online and offline: 1-channel	Online: 1-channel Offline:3-channels
Sensor Dimensions	35 x 35 x 15 (mm)	48 x 29 x 12 (mm)	48 x 29 x 12 (mm)	48 x 29 x 12 (mm)
Sensor Weight	16g	13g	13g	13g
Internal Data logger	no	Yes	yes	yes
Memory Capacity	no	512Mb	1 GB	1 GB or more
ECG Sampling Rate	Selectable: 100, 125, 250, 500, 1000 Hz	Selectable: 100, 125, 250 Hz	Selectable: 100, 125, 250, 500, 1000 Hz	Selectable: 100, 125, 250, 500, 1000 Hz
Resolution	14-bit	14-bit	14-bit	24-bit
Bluetooth	yes	no	yes	yes
Battery	3,7 V Li-ion battery	3,7 V Li-ion battery	3,7 V Li-ion battery	3,7 V Li-ion battery

Table 2: Technological Characteristics comparison Between ECG Sensors

	Web Monitor (Predicate Device)	Virtual Clinic (Subject Device)
Login screen	Yes	Yes
Patient list	Yes	Yes
Document list	Yes	Yes
Doctor info view	Yes	Yes
Doctor list	Yes	Yes
Measurement views - ECG - ECG Report and listing - Blood pressure - Body weight - SpO2	Yes	Yes
Patient management	Yes	Yes
Measurement value limits with notifications	No	Yes
Administration Management	Yes	Yes

Table 3: Comparison Between UI Interfaces features

Copyright© 2015, Mega Electronics Ltd

7. Performance Data Summary

The eMotion Faros ECG Mobile has been fully verified and validated against written test protocols to demonstrate that the design meets the requirements and performs as intended. The test results including product release information summary is documented as a part of the section 011 Summary of Design Control Activities.

Performance is tested and evaluated according to the applicable sections of the following standards:

- EN 60601-1:2006, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
- EN 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ISO 10993-1: 2003, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- EN 60601-2-25:1999 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

8. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing performed supports the substantial equivalence of the device.

9. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the modified device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the eMotion Faros ECG Mobile and the predicate devices do not raise any questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the eMotion Faros ECG Mobile is substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

Copyright© 2015, Mega Electronics Ltd