November 8, 2018

Bittium Biosignals Ltd.
Taneli Vaaraniemi
Quality Manager
Pioneerinkatu 6
Kuopio, Finland FI-70800

Re: K182030
Trade/Device Name: Faros Mobile
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO, DSI, DXH
Dated: October 5, 2018
Received: October 9, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182030

Device Name
Faros Mobile

Indications for Use *(Describe)*
The Faros Mobile system is intended for use in clinical long term ambulatory ECG monitoring, data transfer and analysis. Faros Mobile is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments.
Faros Mobile provides the detection and reporting features appropriate for the indications below
• Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmias.
• Evaluation of patients for ST segment changes
• Evaluation patients with pacemaker
• Evaluating patient rest and stress ECG
• Reporting heart rate variability analysis
• Wireless transmission of patient ECG data and arrhythmia events for further analysis.

Interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The Faros Mobile does not provide interpretive statements.

Faros Mobile is contraindicated for
• Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias
• Pediatric patients weighting less than 10 kg

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.

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Section 005 - Abbreviated 510k Summary

1. Submitter

Bittium Biosignals Ltd.	Bittium Biosignals Ltd. Pioneerinkatu 6 Kuopio, Finland FI-70800
Phone	+358 17 581 7700
Fax:	+358 17 580 0978
Registration number	1000425315
Contact	Taneli Vääräniemi (taneli.vaaraniemi@bittium.com) Quality Manager

2. Date

November 7, 2018

3. Device identification

Device name	Faros Mobile
Trade/Proprietary Name:	Faros ambulatory ECG recorder, telemetric
Common/Usual Name:	Digital Ambulatory ECG recorder, transmitter
Classification Product Code:	MLO - Electrocardiograph, Ambulatory, with Analysis Algorithm
Regulation Classification	870.2800
Subsequent Product Code	DSI - Arrhythmia detector and alarm
Regulation Classification	870.1025
Subsequent Product Code	DXH - Transmitters and Receivers, Electrocardiograph, Telephone
Regulation Classification	870.2920
Class of Device:	Class II
Panel:	Cardiovascular
Device Classification EU:	Class II
Medical Device Directive:	93/42EEC as an amended by 2007/47/EC Certificate issued by VTT Expert services Oy, NB0537

4. Substantial equivalence, predicate device

K140847, CARDIO SPY ECG Holter Systems by LABTECH KFT.

Reference device: technology, design functionality

K143032, eMotion Faros ECG Mobile by Mega Electronics Ltd.

5. Indications for Use Statement

The Faros Mobile system is intended for use in clinical long term ambulatory ECG monitoring, data transfer and analysis. Faros Mobile is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments.

Faros Mobile provides the detection and reporting features appropriate for the indications below

- Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmias.
- Evaluation of patients for ST segment changes
- Evaluation patients with pacemaker
- Evaluating patient rest and stress ECG
- Reporting heart rate variability analysis
- Wireless transmission of patient ECG data and arrhythmia events for further analysis.

Interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The Faros Mobile does not provide interpretive statements.

Faros Mobile is contraindicated for

- Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias
- Pediatric patients weighting less than 10 kg

6. Device Description

Faros Mobile is used for long term registration of a patient's heart electrocardiogram (ECG) and the wireless or wired transmission of the registered electrocardiogram arrhythmia events to a receiver or analysis system running on computer. The device is connected to a patient via electrode leads and the patient wears the device during the recording period and/or while he or she performs normal daily activities. The device is used with commercially available snap ECG electrodes.

Data is transferred to computer via USB. The ECG recording is analyzed at a medical facility using a Cardiac Navigator or Cardiac Explorer software.

In wireless transmission mode, Bluetooth communication protocol enables use of the Faros sensor as a part of a Mobile Cardiac Telemetry (MCT) or Cardiac Event Monitor (CEM) system. Data is transferred from device to companion device. For clarity, all the data is stored on sensor memory when the device operates via Bluetooth. The communication protocol is provided for 3rd party integration purposes.

Device measurement configurations are managed via Faros Device Manager. The application operator can manage measurement configurations which include: ECG and motion data sampling frequencies, ECG channel count, heart rate variability, temperature, auto start and measurement auto stop features. Values for cardiac arrhythmia event detections are handled via Faros Manager application.

Faros Mobile system consists of:

- Faros ECG sensor
    - Bluetooth communication protocol and documentation for implementing interface for data collection from Faros sensor
    - channel and 3-channel cable sets
    - general micro-USB cable for recharging device
- Faros Manager application
- Cardiac Explorer application
- Cardiac Navigator application

7. Comparison of technological characteristics

The following table compares the Faros Mobile to the predicate device with respect to indications for use, technological characteristics and principles of operation providing more information regarding the basis for the determination of substantial equivalence.

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

Table 1: Comparison of characteristics

Manufacturer	Bittium Biosignals Ltd	LABTECH KFT.	Mega Electronics Ltd
Trade name	Faros Mobile	CARDIOSPY ECG Holter Systems	eMotion Faros ECG Mobile
	Subject device	Predicate device	Reference device
510(k) number	K182030	K140847	K143032
Product code and regulation number	DSI - 21 CFR 870.1025	MLO - 21 CFR 870.2800	DXH - 21 CFR 870.2920
Subsequent Product Code and regulation number	DXH - 21 CFR 870.2920 MLO 21 CFR 870.2800	n/a	n/a
ECG channels	1- or 3-channels	1, 2, 3 , 12 -channels	1- or 3-channels
ECG performance standard	IEC 60601-2-47	IEC 60601-2-47	IEC 60601-2-25
RR Algorithm	Yes	Yes	Yes
Cardiac arrhythmia detection	Yes	Yes	No
Event marker	Yes	Yes	Yes
Data transfer	Yes	Yes	Yes
Battery type	Li Ion battery	1x1.2 V AAA NiMH battery (or 1x1.5 V AAA alkaline battery)	Li Ion battery
Software	Cardiac Navigator, Cardiac Explorer	Cardiospy software	LiveECG and Virtual Clinic
Simple, user friendly software with multiple functions	Yes	Yes	Yes
Full disclosure ECG review tool	Yes	Yes	Yes
Precise QRS classification and rhythm analysis	Yes	Yes	No
Arrhythmia analysis, arrhythmia overview	Yes	Yes	No
Atrial Fibrillation analysis	Yes	Yes	No

Table 2: Comparison of indications for use

Manufacturer	Bittium Biosignals Ltd	LABTECH KFT.	Mega Electronics Ltd
Trade name	Faros Mobile	CARDIOSPY ECG Holter Systems	eMotion Faros ECG Mobile
Indications for use	The Faros Mobile system is intended for use in clinical long term ambulatory ECG monitoring, data transfer and analysis. Faros Mobile is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments. Faros Mobile provides the detection and reporting features appropriate for the indications below • Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmias. • Evaluation of patients for ST segment changes • Evaluation patients with pacemaker • Evaluating patient rest and stress ECG • Reporting heart rate variability analysis • Wireless transmission of patient ECG data and arrhythmia events for further analysis. Interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The Faros Mobile does not provide interpretive statements. Faros Mobile is	The Cardiospy ECG Holter System is intended for use in a clinical, by qualified professionals, for patients requiring ambulatory (Holter) monitoring 24, 48, 72, 168 h hours. Such monitoring is most frequently used for purpose of prospective and retrospective cardiac data and arrhythmia analysis. The System, among others, provides the detection and reporting features appropriate to the indications below for children and adults of all ages (up to 2 years): • Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmia. • Evaluation of patients for ST segment changes • Evaluation of patients with pacemakers • Reporting of time domain heart rate variability • Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after MI. or cardiac surgery.) • Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients • Clinical and epidemiological research studies	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.

	contraindicated for • Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias • Pediatric patients weighting less than 10 kg		

8. Performance Data Summary

Faros Mobile submission was written according to and in conformance with FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" released on October 2003. The test reports in the submission demonstrate the Faros Mobile meets its intended use and design requirements.

The verification, validation, and testing activities establish the performance and functionality characteristics of the Faros Mobile. Testing comprised electrical and mechanical safety tests, EMC tests, environmental tests, ECG and algorithm performance tests, usability and functional tests.

Performance data demonstrated that Faros Mobile is effective, secure, safe and suitable for its indication for use, and data has shown conformance to following voluntary FDA recognized standards:

- IEC 60601-1:2005+AMD1:2012, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: 2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-47:2012, Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ISO 10993-1: 2015, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- IEC 60601-1-11:2015, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015, Medical devices -- Application of usability engineering to medical devices
- IEC 62304:2006, Medical device software -- Software life cycle processes
- IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

9. 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.

10. Statement of Substantial Equivalence

Faros Mobile 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 Abbreviated 510(k) submission that the difference between the Faros Mobile and the predicate devices do not raise any new questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Faros Mobile is substantially equivalent to the relevant aspects of the predicate devices in terms of design, principle of operation, performance characteristics, and intended use.