



February 5, 2018

Bettercare S.L.
Bernat Sales
Chief Executive Officer
Xaloc 6
Sabadell, 08203 ES

Re: K171361

Trade/Device Name: BetterCare Platform - Advanced Web Client
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: December 18, 2017
Received: December 21, 2017

Dear Bernat Sales:

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.

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.

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,

A handwritten signature in black ink, appearing to read "M. Zuckerman", is written over a large, light blue "FDA" watermark.

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)

K171361

Device Name

BetterCare Platform - Advanced Web Client

Indications for Use (Describe)

The BetterCare Platform - Advanced Web Client is a software application capable of displaying physiological data and other patient information to clinicians in near real-time through a web browser. The information is captured from patient monitors by the Draeger Infinity Gateway interfaced with the BetterCare Platform and sent through the hospital local area network to wired or wireless devices running the Advanced Web Client application. The information must be analyzed and interpreted by an expert clinician only. The BetterCare Platform is not indicated for use as a real-time monitor.

The BetterCare Platform - Advanced Web Client is intended to display data and waveforms from attached medical devices in a pass-through fashion, the BetterCare Platform - Advanced Web Client is agnostic to the age or condition of patients attached to the medical devices from which data is received. For example, the special requirements for neonatal, pediatric or adult patients are all provided by the medical devices directly attached to the patient. The BetterCare Platform - Advanced Web Client simply reproduces that numeric, waveform and other clinical data provided to it for communications and display.

The BetterCare Platform - Advanced Web Client is installed on compatible desktop and mobile devices, including cellular telephones, and is intended to be used by clinicians to:

- remotely view patient physiological information as captured by Draeger Infinity Gateway
- remotely view waveforms as captured by Draeger Infinity Gateway
- remotely view other patient data as captured by Draeger Infinity Gateway

The BetterCare Platform - Advanced Web Client is not patient connected and is not a primary alarm source. It can display the following physiological data captured by Draeger Infinity Gateway:

- ECG Waveform
- Arterial Pressure Waveform
- SpO2 Waveform
- CO2 Waveform
- Central Venous Pressure Waveform
- Pulmonary Arterial Pressure Waveform
- Right Auricular Pressure Waveform
- Left Auricular Pressure Waveform
- Resp Waveform
- Heart Rate
- Respiratory Rate
- Oxygen Saturation
- Central Venous Pressure
- Systolic Arterial Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Arterial Pressure Invasive
- Systolic Blood Pressure Non invasive
- Mean Blood Pressure Non invasive
- Diastolic Blood Pressure Non invasive
- Systolic Pulmonary Arterial Pressure
- Mean Pulmonary Arterial Pressure
- Diastolic Pulmonary Arterial Pressure

- Right Auricular Pressure

- Left Auricular Pressure

BetterCare Platform Advanced Web Client is intended to be installed on wired and wireless devices, including cellular telephones, and is not intended to be used where such devices are prohibited.

BetterCare Platform Advanced Web Client is intended for use by trained clinicians in hospital environments as a diagnostic aid and not as a replacement for direct viewing of any of the monitoring devices interfaced.

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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K171361 – 510(k) Summary

DATE OF SUBMISSION: 2016-02-26
SUBMITTER NAME: BETTERCARE S.L.
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DEVICE TRADE NAME: BetterCare Platform - Advanced Web Client
COMMON NAME: System, Network And Communication, Physiological Monitors, Web Client, Web Viewer, MView
CLASSIFICATION NAME: Cardiac monitor (870.2300)
PRODUCT CODE: MSX
REGULATION DESCRIPTION: Cardiac monitor (including cardiometer and rate alarm)

PREDICATE DEVICE(S):

- K100133 Airstrip RPM (Airstrip Technologies) - Primary Predicate
- K061994 Web Viewer, Pocket Viewer and Cellular Viewer (General Electric) - Reference Predicate

DEVICE DESCRIPTION:

The BetterCare Platform - Advanced Web Client is a software application capable of displaying physiological data and other patient information to clinicians in near real-time through a web browser. The information is captured by Draeger Infinity Gateway interfaced with the BetterCare Platform and sent through the hospital local area network to wired or wireless devices running the Advanced Web Client application. The information must be analyzed and interpreted by an expert clinician only.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

BetterCare Platform - Advanced Web Client is compared with the following previously cleared devices:

- Airstrip RPM (K122133) - Primary Predicate
- Web Viewer, Pocket Viewer and Cellular Viewer (K061994) - Reference Predicate

Comparison of the proposed devices with the predicate device is summarized in the following table:



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Item	New Device BetterCare Platform - Advanced Web Client	Primary Predicate K122133 Airstrip RPM	Reference Predicate K061994 Web viewer, Pocket Viewer and Cellular Viewer
Intended use	<p>Display of physiologic data and other patient information to clinicians in near real-time through a web browser as captured by Draeger Infinity Gateway interfaced with the BetterCare platform. It is intended to be used by clinicians to:</p> <ul style="list-style-type: none"> - remotely view patient physiological information as captured by Draeger Infinity Gateway - remotely view near real-time waveforms as captured by Draeger Infinity Gateway - remotely view other near real-time patient data as captured by Draeger Infinity Gateway. 	<p>Display of physiologic and other patient information generated by other medical devices and patient information system.</p> <p>AirStrip RPM is intended to be used by clinicians for the following purposes:</p> <ul style="list-style-type: none"> - by using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital - to view the near real-time waveforms remotely - to remotely review other standard or critical near real-time patient data from the monitored system - to provide a request for remote consultation regarding a patient's waveform or other data. 	<p>Display of Information received from other networked devices. It is comprised of a Mobile Care Server and Web Viewer or Pocket Viewer clients</p>
Target population	Clinicians	Clinicians	Clinicians
Communication	Secure Sockets Layer (SSL) via HTTPS	Secure Sockets Layer (SSL) via HTTPS	Secure Sockets Layer (SSL) via HTTPS
Communication Methods	LAN / WLAN Wi-Fi	Cellular Modem, Wi-Fi	Cellular Modem, Wi-Fi
Data Source Location	Hospital	Hospital	Hospital
Security Administration	Yes	Yes	Yes
Where used	Within the hospital where the clinician has wired or wireless access to the hospital local area network.	Anywhere the clinician has remote internet access	Anywhere the clinician has remote internet access.
Client Platforms / Operating systems	Windows 7 and above; iOS 6 and above, Android 4.0 and above	iOS / iPhone	Windows 95/98/ME/NT4.0/2000/XP or MacOS X 10.1 on desktop or portable



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Item	New Device BetterCare Platform - Advanced Web Client	Primary Predicate K122133 Airstrip RPM	Reference Predicate K061994 Web viewer, Pocket Viewer and Cellular Viewer
			computers, PcoketPC, PDA or cellular phone with Windows Moobile 2003 / 5.0 / Phone Edition
Ability to view near real-time data	Yes	Yes	Yes
Physiologic data displayed	<p>Waveform Data</p> <ul style="list-style-type: none"> - ECG Waveform - Arterial Pressure Waveform - SpO2 Waveform - CO2 Waveform - Central Venous Pressure Waveform - Pulmonary Arterial Pressure Waveform - Right Auricular Pressure Waveform - Left Auricular Pressure Waveform - Resp Waveform <p>Near real-time physiological data</p> <ul style="list-style-type: none"> - Heart Rate - Respiratory Rate - Oxygen Saturation - Central Venous Pressure - Systolic Arterial Pressure Invasive - Mean Arterial Pressure Invasive - Diastolic Arterial Pressure Invasive - Systolic Blood Pressure Non invasive - Mean Blood Pressure Non invasive 	<p>Waveform Data</p> <ul style="list-style-type: none"> - ECG Waveform - Blood Pressure Waveform - O2 Waveform - CO2 Waveform <p>Near real-time physiological data</p> <ul style="list-style-type: none"> - Heart Rate - Respiratory Rate - Oxygen Saturation - Intracranial Pressure - Central Venous Pressure - Pulmonary Capillary Wedge Pressure - Cardiac Index - Cardiac Output - Cerebral Perfusion Pressure - Urine Output - Urine / Stool Mix Output - Systolic Blood Pressure Invasive - Mean Arterial Pressure Invasive - Diastolic Blood Pressure Invasive - Systolic Blood Pressure Cuff - Mean Arterial Pressure Cuff - Diastolic Blood Pressure Cuff <p>Other patient information displayed</p> <ul style="list-style-type: none"> - Vasoactive Infusions - Antiarrhythmics - Sedation - Paralytics 	<p>Waveform Data</p> <ul style="list-style-type: none"> - ECG Waveform - Blood Pressure Waveform - O2 Waveform - CO2 Waveform <p>Near real-time physiological data</p> <ul style="list-style-type: none"> - Heart rate - Respiratory Rate - Oxygen Saturation - Intracranial Pressure - Central Venous Pressure - Pulmonary Capillary Wedge Pressure - Cardiac Index - Cardiac Output - Cerebral Perfusion Pressure - Systolic Blood Pressure Cuff - Mean Blood Pressure Cuff - Diastolic Blood Pressure Cuff - Systolic Blood Pressure Invasive - Mean Blood Pressure Invasive - Diastolic Blood Pressure Invasive - Temperature



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Item	New Device BetterCare Platform - Advanced Web Client	Primary Predicate K122133 Airstrip RPM	Reference Predicate K061994 Web viewer, Pocket Viewer and Cellular Viewer
	<ul style="list-style-type: none"> - Diastolic Blood Pressure Non invasive - Systolic Pulmonary Arterial Pressure - Mean Pulmonary Arterial Pressure - Diastolic Pulmonary Arterial Pressure - Right Auricular Pressure - Left Auricular Pressure 	<ul style="list-style-type: none"> - Laboratory Data including: <ul style="list-style-type: none"> o Blood Gas o Chemistry o Hematology o Coagulation - Allergies - Medication 	
Contraindications	BetterCare Platform - Advanced Web Client is intended to be installed on wired and wireless devices, including cellular telephones, and is not intended to be used where such devices are prohibited.	AirStrip RPM software is intended for installation on cellular telephones and other wireless devices and is not intended for use anywhere cellular telephones or wireless devices are prohibited.	N/A
Principal operation of	BetterCare Platform - Advanced Web Client works by retrieving patient data from the hospital monitoring system and providing that data to the user's computer or device over the hospital local area network.	AirStrip RPM works by retrieving patient data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet.	Pocket Viewer / Web Viewer works by retrieving data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet.
Client devices	Desktop or portable computers or mobile hand-held wireless devices running a web browser.	iPhone	Desktop or portable computers or Windows mobile hand held PDA

Table 5.1 Summary comparison of characteristics and features – proposed and predicate devices



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INTENDED USE / INDICATIONS FOR USE:

The BetterCare Platform - Advanced Web Client is a software application capable of displaying physiological data and other patient information to clinicians in near real-time through a web browser. The information is captured by Draeger Infinity Gateway interfaced with the BetterCare Platform and sent through the hospital local area network to wired or wireless devices running the Advanced Web Client application. The information must be analyzed and interpreted by an expert clinician only. The BetterCare Platform is not indicated for use as a real-time monitor.

The BetterCare Platform - Advanced Web Client is installed in compatible desktop and mobile devices, including cellular telephones, and is intended to be used by clinicians to:

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- Right Auricular Pressure
- Left Auricular Pressure

BetterCare Platform - Advanced Web Client is intended to be installed on wired and wireless devices,



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including cellular telephones, and is not intended to be used where such devices are prohibited.

BetterCare Platform - Advanced Web Client is intended for use by trained clinicians in hospital environments as a diagnostic aid and not as a replacement for direct viewing of any of the monitoring devices interfaced.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The proposed device has been designed, developed, tested, verified and validated according to documented procedures and specific protocols in line with the following FDA guidance documents:

- FDA Guidance on the Content of Premarket Submissions for Software Contained in Medical Devices
- FDA Guidance on the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- FDA Guidance - Cybersecurity for Networked Medical Devices Containing Off-the-shelf (OTS) Software
- FDA Guidance - General Principles of Software Validation
- FDA Guidance - Off-the-shelf Software Use in Medical Devices

Design and development included identification, evaluation and control of potential hazards as per standard ISO 14971. Development, integration, verification and validation testing have been successfully completed following standard ISO 62304.

Testing included verification of all available listed waveform and near real-time data points. Known data sets were gathered using Draeger Infinity Gateway interfaced with BetterCare Platform and displayed on Advanced Web Client. All waveforms and near-real time physiological information points were verified and in all cases, Advanced Web Client displayed data points accurately.

SUMMARY DISCUSSION OF CLINICAL DATA:

No clinical data is submitted to support this premarket notification.

CONCLUSIONS:

We believe the intended use, the indications for use and performance of the BetterCare Platform - Advanced Web Client is substantially equivalent to the intended use, indications for use and performance of the primary predicate device. We also believe that the BetterCare Platform - Advanced Web Client does not suppose any new or increased risk compared with the primary predicate device. Based on the information included in this submission, we conclude that BetterCare Platform - Advanced Web Client is substantially equivalent to the stated primary predicate device.