



Food and Drug Administration
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August 27, 2015

Cardioline S.p.A
Mr. Emanuele Ercoli
Via De Zinis, 6
38011 Cavareno (TN), Italy

Re: K150289

Trade/Device Name: Cardioline HD+
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 20, 2015
Received: July 22, 2015

Dear Emanuele Ercoli:

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

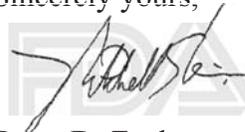
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go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

K150289

Device Name

HD+

Indications for Use (Describe)

HD+ is a physiological ECG acquisition module. HD+ transmits wireless, via Bluetooth to a PC or Tablet, the data acquired, without making any analysis or filtering on the data acquired.

HD+ acquires 12-lead ECG waveforms meeting the standards for clinical and diagnostic applications (AAMI, ANSI, AHA, ACC) and offers full ECG acquisition.

HD+ is designed to acquire and transmit a high quality ECG data allowing the patient to be free to moving (without cable connected to the processing unit).

The HD+ transmits the acquired physiological signals in real-time to a computer/device where a compatible application is installed.

All data acquired are sent via Bluetooth to a receiver that it can be a PC, tablet or device capable of receiving BT data.

The ECG is transmitted verbatim to the receiving system, without LSB or sampling adjustment. It is up to the receiving system/application to perform the necessary processing such as (but not limited to) LSB scaling, signal filtering, Resting ECG analysis etc...

The device HD+ is intended to be used on adult and on all pediatric patients.

The device is intended for use by qualified, trained nurses and physicians operating in hospitals, clinics and medical practices.

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.

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510(k) SUMMARY HD+ - K150289

1. SUBMITTER

CARDIOLINE S.p.A
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Contact Person: Mr Emanuele Ercoli
Date prepared: December 12, 2014

2. DEVICE

Name of Device: Cardioline HD+
Common or Usual Name: HD+
Classification Name: Physiological Signal Acquisition Device
Regulatory Class: II
Product Code: CFR 870.2910 Transmitter and Receivers, Physiological Signal, Radiofrequency, DRG

3. PREDICATE DEVICE

Manufacturer name	Applicant Name	Predicate Device	510(k) Number
Cardioline S.p.A.	Cardioline S.p.A.	Mortara X-12	K974149
Cardioline S.p.A.	Cardioline S.p.A.	Et medical devices S.p.A.	K082124

4. DEVICE DESCRIPTION

The HD+ is a digital portable acquisition device which can acquire the electrocardiographic signal of 12 standard leads. Connected with a receiver via Bluetooth, sends the data to the host but doesn't make any analysis or filtering. It's the host (PC or Tablet separated by HD+) which make the analysis. HD+ is not intended to control or analysis heart function and/or to diagnose the patient's health status. Analysis program on the host is a separate product not marketed with the HD+.

HD+ is a wireless acquisition device, to be primarily used as common ECG front-end for PC/tablet (Windows/MAC OS/other) standard platforms (both for Resting ECG and Stress ECG applications). Depending on performance/price ratio, HD+ could be also used with selected embedded electrocardiographs.

HD+ allow the patient to be ambulatory.

HD+ uses a standard Bluetooth data transmission technology to transmit 12-lead ECG data over a proximity range, providing perfect electrical insulation and freedom of movement for the patient.

The device implements the wireless communication via Bluetooth wireless technology. The Bluetooth radio protocol is implemented by a dedicated chipset developed by Bluegiga Technologies (WT-12). The device is a BT 2.1 compliant device. Its rated emission power is 3.46 dBm and uses the Bluetooth radio bandwidth (2402-2480 Hz, 79 channels).

The device function consists of acquiring and wirelessly transmitting ECG signal for displaying, processing and presenting ECG signal for the purpose of supporting the diagnose of patient conditions.

The device does not store nor does associate patient identification data to the acquired signal, nor does it perform analysis on such signal.

The device transmits a continuous stream of ECG samples at rate of 500 s/s or 1000 s/s and a resolution < 1uV/LSB. The bitrate required by the application is ~90 kbit/s at 500 s/s and ~180 kbit/s at 1000 s/s.

In order to support the application data throughput, the device implements the Bluetooth Serial Port Profile (SPP) with EDR (Enhanced Data Rate), which nominally provides a bandwidth up to 2 mbit/s.

The SPP adopted by the device ensures that data is either received correctly or not received at all. It is up to the host application to detect packet losses, handling the data gaps appropriately (e.g. by filling the stream with invalid dummy samples, signaling transmission errors etc...). This approach has been preferred over enabling the data retransmission (supported by the module) to reduce the data jitter and transmission delay.

HD+ uses standard 12 lead ECG cable to acquire the physiological signal to the patient.

HD+ is light and compact, comfortable to wear, minimizing motion artifacts caused by traditional electrodes and patient cables.

HD+ offers full ECG acquisition - meeting the standards used in clinical and diagnostic applications (AAMI, ANSI, AHA, ACC).

HD+ uses a LED indicator to comfortably monitor the link status (off when unit is powered down, blinking when unit is attempting to connect with the receiver, steady when unit is connected with the receiver).

HD+ uses a programmable key to send macro commands to the receiving system (i.e. acquire and print an ECG).

Low-power technology allows continuous usage of the device for more than 10 hours (from full battery charge).

The HD+ transmits the acquired data in real-time to a computer where one of the compatible CARDIOLINE software is installed. The results of the analysis must always be validated by qualified, trained medical personnel and the device is intended for use in a medical environment. HD+ is intended to be used on adult and all pediatric patients. The device must be handled with care by taking all the necessary precautions in order to prevent and avoid shocks, vibrations, heat sources, liquids and anything else that may damage it.

5. INDICATION FOR USE

HD+ is a physiological ECG acquisition module. HD+ transmits wireless, via Bluetooth to a PC or Tablet, the data acquired, without making any analysis or filtering on the data acquired.

HD+ acquires 12-lead ECG waveforms meeting the standards for clinical and diagnostic applications (AAMI, ANSI, AHA, ACC) and offers full ECG acquisition.

HD+ is designed to acquire and transmit a high quality ECG data allowing the patient to be free to moving (without cable connected to the processing unit).

The HD+ transmits the acquired physiological signals in real-time to a computer/device where a compatible application is installed.

All data acquired are sent via Bluetooth to a receiver that it can be a PC, tablet or device capable of receiving BT data. The ECG is transmitted verbatim to the receiving system, without LSB or sampling adjustment. It is up to the receiving system/application to perform the necessary processing such as (but not limited to) LSB scaling, signal filtering, Resting ECG analysis etc...

The device HD+ is intended to be used on adult and on all pediatric patients.

The device is intended for use by qualified, trained nurses and physicians operating in hospitals, clinics and medical practices.

6. TABULAR COMPARISON WITH PREDICATE DEVICES

FEATURES	CARDIOLINE HD+	MORTARA X-12	ET MEDICAL DEVICE SpA CARDIETTE MICROTREL
Intended use	HD+ is designed to acquire and transmit ECG data. HD+ transmits wireless, via Bluetooth to a PC or Tablet, and doesn't make any analysis or filtering on the data acquired.	Is designed to acquire, transmit and receive diagnostic quality ECG data while allowing the patient to be ambulatory in a clinical setting.	Is intended for use in routine ECG recording in physician practice. The acquired ECG can be send to a personal computer also via Bluetooth. It doesn't include any interpretation tools or analysis program.
Target population	Adults and pediatric patients	Adults and neonatal patients	Adults
Safety standards	IEC 60601-1 IEC 60601-2-25 CB scheme	IEC 60601-1 IEC 60601-2-25	IEC 60601-1 IEC 60601-2-25
EMC standards	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
RADIO standards	ETSI EN 300 328 ETSI EN 301 489 -1 ETSI EN 301 489 -17 ETSI EN 300 440 -2 FCC CFR47 Part 15 (US)	FCC CFR47 Part 15 (US) Other standards not specified.	ETSI EN 300 328 ETSI EN 301 489 -1 ETSI EN 301 489 -17 FCC CFR47 Part 15 (US)
ECG Leads	12 Leads	12 Leads	12 Leads
Sampling Rate	1000 samples/second/channel for analysis	500 samples/second/channel transmission for recording and analysis	500 samples per second
Leads Connector	Single connector	Single block	Cable with banana end
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
A/D Conversion	24 bit	Not specified	11 bit
Data Resolution	20 bit, < 1uV/LSB	Not specified	Not specified
Input Range	+/-400mV @ < 1uV/LSB	Not specified	± 300 mV @ 0 Hz.± 5 mV in the through band
Bandwidth	0.05 – 300 Hz	Not specified	0.05Hz – 150Hz
CMRR	115 dB	Not specified	> 100 dB
Defibrillator Protection	AAMI/IEC standards	Defibrillator protected when used with Mortara Instrument patient cable	Protection against defibrillation with Discharging resistance in the patient cable
Pacemaker detection	Hardware detection coupled with convolution digital filtering	Yes	Not specified
Wireless System	Bluetooth 2.1 + EDR	Digital radio transmission using a proprietary encoding scheme	(in Bluetooth version) Bluetooth 1.0
Patient Cable	10 wire single connector	Single block 10 lead	10 wire cable with banana end
Batteries	2 x 1,5 standard AAA.	2 x AA alkaline batteries.	4 AA ultra alkaline batteries

	Battery life 10 hours	Battery life 30 hours	or rechargeable NiMh (at least 2500mAh) Battery life > 7 hours
IP Degree	IP 40 / IP 42 with silicon cover	Not specified	IP 20
Environmental	<ul style="list-style-type: none"> - Temperature between +10 and +40 °C inclusive - Relative humidity between 25 and 95 % inclusive (without condensation) - Atmospheric pressure between 700 and 1060 mbar 	<ul style="list-style-type: none"> - Operating temperature between 10 to 32 °C - Humidity between 20 to 80 % - Atmospheric pressure between 700 and 1060 mbar 	<ul style="list-style-type: none"> - Temperature between +10 and +40 °C inclusive - Relative humidity between 25 and 95 % inclusive (without condensation) - Atmospheric pressure between 700 and 1060 mbar
Storage environmental conditions	<ul style="list-style-type: none"> - Temperature between -10 e +40 °C inclusive - Relative humidity between 25 and 95 % inclusive (without condensation) - Atmospheric pressure between 500 and 1060 mbar inclusive 	<ul style="list-style-type: none"> - Temperature between 0 e +45 °C - Relative humidity between 10 and 90 % inclusive (without condensation) - Atmospheric pressure between 700 and 1060 mbar inclusive 	<ul style="list-style-type: none"> - Temperature between -10 e +40 °C inclusive - Relative humidity between 25 and 95 % inclusive (without condensation) - Atmospheric pressure between 500 and 1060 mbar inclusive
Where used By	Hospitals, Clinics. Nurse, Physician and trained medical personnel	Hospitals, Clinics Not specified	Hospitals, Clinics Physician and trained medical personnel

7. PERFORMANCE DATA

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

Full safety test according to IEC 60601-1 and IEC 60601-2-25 have been performed on the device. These tests have shown full compliance with these devices.

The device has been subjected to Electromagnetic Compatibility testing procedure according to EN 60601-1-2 standard. Tests have shown full compliance with this standard.

The Bluetooth module complies with ETSI EN 300 328, ETSI EN 301 489-1 and ETSI EN 301 489-17 standards concerning the radio equipment and telecommunication terminal equipment. Tests are carried out also according to FCC CFR 47 Part 15 rules. Tests have shown full compliance with these standards.

The performance tests are carried out according to IEC 60601-2-51 and the performance tested are:

- Patient Derivation Polarity
- Minimum System Switch Leads
- Goldberger and Wilson Derivations
- Input Impedance and Circuit Lead
- Common Mode Rejection
- Noise Level
- Writing Speed and Trace Width
- Channels Interaction
- High Frequency Response
- Low Frequency Response
- Linearity and Dynamic Range
- Minimal Signal Response
- Sampling and Resolution
- Recording Speed
- ECG Distortion
- Impulse Visibility of Pace-Maker
- Internal Electrical Source Requirements

8. CONCLUSION

The safety features of the CARDIOLINE HD+ are identical to those of the predicate device MORTARA X-12 and CARDIETTE MICROTEL.

The performance of HD+ are basically similar to the predicate and are summarized in table above. Like Cardiette Microtel, the subject device HD+, has no parameters computation and interpretation program implemented on device and uses, for the Cardiette Bluetooth version, the same transmission mode (data transmitted by Bluetooth).

Like Mortara X-12 is designed to acquire and transmit quality ECG data.

The Standards Leads Acquired are the same to both predicate devices.

The intended use of CARDIOLINE HD+ is the same of Mortara X-12 excluding the transmission protocol which is the same of Cardiette Microtel.

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in the substantial equivalence. HD+ is only an acquisition device without an analysis, diagnosis and monitoring features, so is not expected clinical evaluation.