May 15, 2023

Cardioline S.P.A
℅ Brian Brenegan
Regulatory Correspondent
CYA Medical Device Consulting, LLC
34340 Venice Beach Road
Oconomowoc, Wisconsin 53066

Re: K220526
Trade/Device Name: HD+12, HD+15
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: April 14, 2023
Received: April 14, 2023

Dear Brian Brenegan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220526

Device Name
HD+12, HD+15

Indications for Use *(Describe)*
The function of the device is the acquisition and transmission of the ECG signal in order to support diagnosis of the patient's conditions.

HD+ is a wireless or USB (with appropriate option) ECG acquisition device, to be used primarily as common front-end for standard PC/tablet platforms (Windows/MAC OS/others), for resting ECG applications.

The device implements wireless communication via Bluetooth wireless technology or wired with USB communication. With both connection modes, HD+ sends the data to the receiver device without performing any analysis or filtering. HD+ is not intended for monitoring or analysis of the cardiac function or to diagnose the patient's health condition. Display, print and analysis applications on the receiver device are separate products. HD+ is not able to permanently store the acquired data, therefore it does not work unless a connection has been established with a receiver application. Furthermore, HD+ does not collect any of the patient's sensitive data (patient's name, age, previous health conditions etc.).

HD+ detects the QRS complexes and transmit the results to the receiving device. The QRS detection function is intended for patients aged 12 years or older.

*HD+ is indicated for the acquisition of ECG signals with the patient in resting conditions, for example for diagnostic ECG's and rhythm strips
*HD+ is suitable for working at high altitudes, with restrictions.
*HD+ is intended for use on patients, with no limits of age or gender, except for the HR detector function which is intended for patients 12 years or older
*HD+ is intended for use in medical facilities (hospitals, clinics), at home or emergency settings (ambulances).
*HD+ is intended for use by a physician, nurse or other healthcare professional (e.g., ECG technician) who acts following orders by a physician or authorized nurse, including when operated in home environments
*HD+ is not intended for real-time monitoring of vital physiological parameters.

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+12, HD+15

1. SUBMITTER

CARDIOLINE S.p.A
Via Linz, 151
3838121 Trento Italy
T +39 0461 96821

Contact Person: David Lombardi
Date prepared: 05 May 2023

2. DEVICE

Name of Device: Cardioline HD+12, HD+15
Common or Usual Name: HD+
Classification Name: Physiological Signal Acquisition Device
Regulatory Class: II
Product Code: DRG CFR 870.2910 Transmitter and Receivers, Physiological Signal, Radiofrequency

3. PREDICATE DEVICE

Manufacturer name	Applicant Name	Predicate Device	510(k) Number
Cardioline S.p.A.	Cardioline S.p.A.	HD+	K150289

4. DEVICE DESCRIPTION

HD+12 and HD+15 are the new revisions of Cardioline's HD+ wireless acquisition module. The HD+ is a digital portable acquisition device which can acquire the electrocardiographic signal of 12 and 15 standard leads. Connected with a receiver via Bluetooth or USB (with the optional USB connector), the HD+ performs no analysis or filtering but sends acquired data to a host application where the User Interface is implemented. By default, the device includes a demo compatible software "HD+ Display" whose purpose is providing a UI for viewing the traces acquired by HD+. HD+ Display provides a simple UI, sufficient to configure the application to connect to an HD+ device via Bluetooth (the application automatically detects if an HD+ device is connected via USB and does not require additional configuration) and sufficient to display the ECG traces as received by HD+. HD+ Display does not provide any clinical functionality; therefore, it does not provide any capability to store, print or analyze the acquired ECG.

It is the host (PC or Tablet separated by HD+) which performs the analysis. HD+ is not intended to control or analysis heart function and/or to diagnose the patient's health status. The 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 ECG front-end acquisition device for PC/tablet (Windows/MAC OS/Android/iOS/others) standard platforms for Resting ECG applications. Depending on performance/price ratio, HD+ could be also used with selected embedded electrocardiographs. HD+ allows the patient to be ambulatory.

HD+ uses a standard Bluetooth data transmission technology to transmit 12-lead and 15-lead ECG data over a proximity range, providing 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 module, FCC compliant. In order to support the data transmission speed of the application, the device implements the BLE 5 protocol with DLE (Data Length Extension) and 2M PHY (bandwidth up to 2 Mbit/s). The minimum specifications of the device connected to HD+ is BLE 4.2 to support the band required by acquisitions at 500 s/s. In order to operate at 1000 s/s, the connected device must be BLE 5.0 (or higher) and have a compatible 2M PHY radio (2 Mbit/s). Alternatively, in addition to Bluetooth connectivity described above, the HD+ has an optional USB interface that can be used to transmit data. The USB interface provides an electrical insulation offering two means of patient protection (2MPP), allowing HD+ to be connected to any IT equipment conforming to IEC 62368-1.

The HD+ function consists of acquiring and transmitting ECG signals for display processing and presenting ECG signals for the purpose of supporting the diagnosis of patient conditions. The device does not store nor does it associate patient identification data to the acquired signal, nor does it perform analysis on such signal. The HD+ is used solely for transmission of ECG signals from patient to a host analysis platform.

The HD+ transmits a continuous stream of ECG samples at a rate of 500 s/s or 1000 s/s, with a resolution of 0.817 uV/LSB or 2.495 uV/LSB, selectable by the calling application of the host analysis platform. The average required transmission throughput for sending 15 leads at 1000 s/s is approximately 155kbit/s, while to send 12 leads at 500 s/s the required throughput is approximately 54 kbit/s. BLE 5 2M PHY provides the bandwidth needed to support the maximum required throughput.

The BLE communication link 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 or 15 lead ECG cables to acquire the physiological signal from 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+ continuously transmits the acquired data to a computer platform where compatible software, a Host Application authorized by Cardioline, is installed that acts as its User Interface. As an example of such Host Application, the device includes a compatible demo Windows application “HD+ display” from Cardioline to visualize the ECG traces and check the functionality of the HD+. The results of the analysis must always be validated by qualified, trained medical personnel and the HD+ 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

The function of the device is the acquisition and transmission of the ECG signal in order to support diagnosis of the patient’s conditions.

HD+ is a wireless or USB (with appropriate option) ECG acquisition device, to be used primarily as common front-end for standard PC/tablet platforms (Windows/MAC OS/others), for resting ECG applications.
The device implements wireless communication via Bluetooth wireless technology or wired with USB communication. With both connection modes, HD+ sends the data to the receiver device without performing any analysis or filtering.

HD+ is not intended for monitoring or analysis of the cardiac function or to diagnose the patient's health condition. Display, print and analysis applications on the receiver device are separate products. HD+ is not able to permanently store the acquired data, therefore it does not work unless a connection has been established with a receiver application. Furthermore, HD+ does not collect any of the patient's sensitive data (patient's name, age, previous health conditions etc.).

HD+ detects the QRS complexes and transmit the results to the receiving device. The QRS detection function is intended for patients aged 12 years or older.

- HD+ is indicated for the acquisition of ECG signals with the patient in resting conditions, for example for diagnostic ECG's and rhythm strips
- HD+ is suitable for working at high altitudes, with restrictions.
- HD+ is intended for use on patients, with no limits of age or gender, except for the HR detector function which is intended for patients 12 years or older
- HD+ is intended for use in medical facilities (hospitals, clinics), at home or emergency settings (ambulances).
- HD+ is intended for use by a physician, nurse or other healthcare professional (e.g., ECG technician) who acts following orders by a physician or authorized nurse, including when operated in home environments
- HD+ is not intended for real-time monitoring of vital physiological parameters.

6. TABULAR COMPARISON WITH PREDICATE DEVICES

FEATURES	CARDIOLINE HD+12, HD+15	CARDIOLINE HD+	Comparison
Intended use	The function of the device is the acquisition and transmission of the ECG signal in order to support diagnosis of the patient's conditions. HD+ is a wireless or USB (with appropriate option) ECG acquisition device, to be used primarily as common front-end for standard PC/tablet platforms (Windows/MAC OS/others), for resting ECG applications.	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	Similar – function of the device remains the same, addition of use environments (home and ambulance), addition of use by a physician, nurse or

	The device implements wireless communication via Bluetooth wireless technology or wired with USB communication. With both connection modes, HD+ sends the data to the receiver device without performing any analysis or filtering. HD+ is not intended for monitoring or analysis of the cardiac function or to diagnose the patient's health condition. Display, print and analysis applications on the receiver device are separate products. HD+ is not able to permanently store the acquired data, therefore it does not work unless a connection has been established with a receiver application. Furthermore, HD+ does not collect any of the patient's sensitive data (patient's name, age, previous health conditions etc.). HD+ detects the QRS complexes and transmit the results to the receiving device. The QRS detection function is intended for patients aged 12 years or older. ▪ HD+ is indicated for the acquisition of ECG signals with the patient in resting conditions, for example for diagnostic ECG's and rhythm strips ▪ HD+ is suitable for working at high altitudes, with restrictions. ▪ HD+ is intended for use on patients, with no limits of age or gender, except for the HR detector function which is intended for patients 12 years or older ▪ HD+ is intended for use in medical facilities (hospitals,	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.	other healthcare professional (e.g., ECG technician) who acts following orders by a physician or authorized nurse, addition of wired connection option

	clinics), at home or emergency settings (ambulances). ▪ HD+ is intended for use by a physician, nurse or other healthcare professional (e.g., ECG technician) who acts following orders by a physician or authorized nurse, including when operated in home environments ▪ HD+ is not intended for real-time monitoring of vital physiological parameters.		
Target population	Adults and pediatric patients	Adults and pediatric patients	Same
Safety standards	IEC 60601-1 IEC 60601-2-25 IEC 60601-1-11	IEC 60601-1 IEC 60601-2-25 CB scheme	Additional standard for home use
EMC standards	IEC 60601-1-2	IEC 60601-1-2	Same
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)	ETSI EN 300 328 ETSI EN 301 489 -1 ETSI EN 301 489 -17 ETSI EN 300 440 -2 FCC CFR47 Part 15 (US)	Same
ECG Leads	12 and 15 Leads	12 Leads	Optional 3 additional leads
Sampling Rate	500 and 1000 samples/second/channel for analysis	1000 samples/second/channel for analysis	Allows for downgrading if the Bluetooth link does not provide sufficient bandwidth
Leads Connector	Single connector	Single connector	Same
Standard Leads Acquired	12-leads (I, II, III, aVR-L-F, V1-6) 15-leads (I, II, III, aVR-L-F, V1-6, E1-2-3)	I, II, III, aVR-L-F, V1-6	Optional 3 additional leads

A/D Conversion	24 bit	24 bit	Same
Data Resolution	HiRES mode: <1 µV/LSB (@500 c/s) StdRES mode: ~2.5 µV/LSB	20 bit, < 1uV/LSB	HiRES operating mode equivalent to predicate device. StdRES mode reduces the resolution in exchange for higher dynamic range
Input Range	HiRES mode: +/- 330mV StdRES mode: +/- 500 mV	+/-400mV @ < 1uV/LSB	HiRES operating mode equivalent to predicate device. StdRES mode reduces the resolution in exchange for higher dynamic range
Bandwidth	Performances equivalent to 0.05-150 Hz (@ 500 c/s) Performances equivalent to 0.05-300 Hz (@ 1000 c/s)	0.05 – 300 Hz	Same
CMRR	≥100dB	115 dB	Equivalent performance
Defibrillator Protection	AAMI/IEC standards	AAMI/IEC standards	Same
Pacemaker detection	Software on 128K c/s simultaneous on lead pairs (I, II), (V4, V5) and (E1, E2) (for 13 wire cable). Impulse duration range: 0.2 ms – 2 ms Impulse width range: 2mV – 250mV Estimate of pacemaker spike duration and amplitude	Hardware detection coupled with convolution digital filtering	Increased detection sensitivity, requirements of IEC 60601-2-25 met.

Wireless System	BLE 5 or higher with DLE (Data Length Extension) and radio with 2M PHY support (for 1000 c / s) BLE 4.2 or higher with DLE (for 500 c / s)	Bluetooth 2.1 + EDR	Updated to most current Bluetooth version
USB Communication	USB Communication Device Class (RS-232 port emulation)	None	Addition of USB option
Patient Cable	10 wire replaceable wire patient lead 13 wire replaceable patient cable	10 wire single connector	Additional cable for HD+15 enabling the acquisition of the 3 additional leads
Batteries	2 x 1,5 standard AAA. Battery life 10 hours	2 x 1,5 standard AAA. Battery life 10 hours	Same
IP Degree	IP 40 / IP 42 with silicon cover	IP 40 / IP 42 with silicon cover	Same
Environmental	Temperature: 0 to 40 °C Relative humidity: 15 to 95 % (without condensation) Atmospheric pressure: 540 mbar - 1060 mbar (Bluetooth); 700 mbar - 1060 mbar (USB)	Temperature: 10 to 40 °C Relative humidity: 25 to 95 % (without condensation) Atmospheric pressure: 700 to 1060 mbar	Similar
Storage environmental conditions	Temperature and humidity: -40 °C to +5 °C without relative humidity control ; +5 °C to +40 °C, up to 90 % relative humidity, without condensation ; 40 °C to 70 °C with water vapour pressure up to 50 hPa; Atmospheric pressure: 540 mbar; 1060 mbar	Temperature: -10 to +40 °C Relative humidity: 25 to 95 % (without condensation) Atmospheric pressure: 500 to 1060 mbar	Similar
Where used By	Hospitals, Clinics, Home, Ambulance by a physician, nurse or other healthcare professional (e.g., ECG technician) who acts following orders by a physician or authorized nurse	Hospitals, Clinics by Nurse, Physician and trained medical personnel	Similar – addition of home and ambulance and use by a physician, nurse or other healthcare professional (e.g., ECG technician) who acts

			following orders by a physician or authorized nurse

7. PERFORMANCE DATA

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

Full safety test according to IEC 60601-1, 60601-1-11, and IEC 60601-2-25 have been performed on the device. These tests have shown full compliance with these standards.

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 also carried out 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 60601-2-25 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+12 and HD+15 are identical to those of the predicate device CARDIOLINE HD+.

The fundamental function and performance of HD+12 and HD+15 are the same as the predicate with additional features and are summarized in the table above.

The conclusions drawn from the performance tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the substantial equivalence. HD+12 and HD+15, like the predicate HD+, is only an acquisition device without an analysis, diagnosis and monitoring features, so clinical evaluation is not required.