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

November 2, 2016

Cardioline S.p.A
% Alessandro Peluso
Official Correspondent
Studio Tecnico Ing. Peluso
Via Prati 1/2
Zola Predosa-localita Ponte Ronca- Bologna, 40069 IT

Re: K160746
Trade/Device Name: Cardioline touchECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 14, 2016
Received: April 15, 2016

Dear Alessandro Peluso:

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.

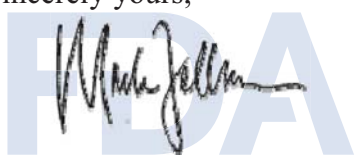
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160746

Device Name
Cardioline touchECG

Indications for Use *(Describe)*

touchECG is designed to check and diagnose cardiac function. However, a physician must validate the results of the analysis run by the ECG.

touchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use by health professional in emergencies (ambulances).

touchECG is intended to be used in conjunction with CARDIOLINE HD+ device.

- The device analyzes, displays and prints out electrocardiograms. The ECG's are acquired from CARDIOLINE HD+ device.
- The device interprets the data for review by a physician.
- The device must be used by a physician or by health professionals on behalf of an authorized doctor in clinical facilities. It is not intended as the only means for determining the diagnosis.
- The device's interpretation of the ECG analysis is only significant if used together with an additional analysis by the physician and by an assessment of all the patient's important data.
- The device can be used on adults patients.
- The device must not be used as a physiological monitoring of vital signs.

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.

510(k) SUMMARY touchECG – K160746

1. SUBMITTER

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38121 Z.I. Spini di Gardolo (TN), Italy

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Contact Person: Mr Emanuele Ercoli
Date prepared: February 29, 2016

2. DEVICE

Name of Device: Cardioline touchECG
Common or Usual Name: touchECG
Classification Name: Electrocardiograph
Regulatory Class: II
Product Code: CFR 870.2340 Electrocardiograph, DPS

3. PREDICATE DEVICE

Manufacturer name	Applicant Name	Predicate Device	510(k) Number
Cardioline S.p.A.	Cardioline S.p.A.	Mortara RScribe Electrocardiograph	K120865
Cardioline S.p.A.	Cardioline S.p.A.	Shenzhen Mindray Bio-medical Electronics Co., Ltd - Passport Series Patient Monitors	K152902

4. LIST OF APPLICABLE STANDARDS

Below a complete list of applicable recognized standards that touchECG is complied:

IEC 60601-2-25:2011	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs. (Cardiovascular)
ISO 14971:2007+R(2010)	Medical Devices - Applications Of Risk Management To Medical Devices.
IEC 62304:2015	Medical Device Software - Software Life Cycle Processes.
IEC 62366:2014	Medical Devices - Application Of Usability Engineering To Medical Devices.

5. DEVICE DESCRIPTION

touchECG is a multichannel interpretative electrocardiograph designed to check and diagnose cardiac function. However, the results of the analysis run by the ECG must be validated by a cardiologist.

touchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use in emergencies (ambulances).

touchECG is intended to be used in conjunction with CARDIOLINE HD+ device (K150289). The CARDIOLINE HD+ device is the device that acquire the ECG signal and send it, via Bluetooth, to the PC in which the touchECG software is installed. touchECG software is designed to works solely with CARDIOLINE HD+ device. The analysis of ECG traces and the automatic interpretation are performed on the PC, and must always be validated by a Cardiologist. The device can't do diagnosis by itself, but only shows the results of interpretation according to Glasgow program.

The device must be used by a doctor or by specialized staff on behalf of an authorized doctor in clinical facilities. It is not intended as the only means for determining the diagnosis.

touchECG is a 12-lead diagnostic electrocardiograph which displays, acquires, prints and stores ECG traces for adults. It also calculates the principal global ECG parameters.

The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria for patients of different age, sex and race. If this option is enabled, the algorithm can provide the physician of reference with an automatic interpretation generating diagnostic messages in the ECG report.

For further information on the resting ECG interpretation algorithm, see the Instruction Manual for doctors for its use with adults.

In the touchECG software, the subject device, the Glasgow Interpretation Algorithm is always loaded on the device. It can be enabled or not, depends on the customer request. Only Cardioline can enable or disable the Glasgow Algorithm.

In case the Glasgow is disabled the text of the automatic interpretation is not printed, but the measurements on the ECG traces are executed by the Glasgow algorithm.

The device installs on any PC, tablet or notebook with the minimum requisites shown below:

Operating System - Windows 7, Windows 8.1, Windows 10

Processor - Intel I5 or higher

RAM - 4GB or more

Free space on Hard Disk - 3GB or more

Monitor - 640 x 480 pixel or more

Bluetooth - Bluetooth 2.1 +EDR

Printer - Laser (colour/BW)

Printing paper: A4, Letter

Interpretation Algorithm: Glasgow algorithm

Additional applications - Email application which supports the EML format (only required for the email File Upload feature)

It prints out in the following formats: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channel in automatic mode, and 3, 6 or 12 printout channels of the rhythm strip.

The device doesn't have other hardware components or accessories. touchECGis intended to be used in conjunction with CARDIOLINE HD+ device (K150289 that acquires the ECG signal and transmits it.

touchECG is a software medical device provided on a CD support

6. INDICATION FOR USE

touchECG is designed to check and diagnose cardiac function. However, a physician must validate the results of the analysis run by the ECG.

touchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use by health professional in emergencies (ambulances).

touchECG is intended to be used in conjunction with CARDIOLINE HD+ device.

- The device analyzes, displays and prints out electrocardiograms. The ECG's are acquired from CARDIOLINE HD+ device.
- The device interprets the data for review by a physician.
- The device must be used by a physician or by health professionals on behalf of an authorized doctor in clinical facilities. It is not intended as the only means for determining the diagnosis.
- The device's interpretation of the ECG analysis is only significant if used together with an additional analysis by the physician and by an assessment of all the patient's important data.
- The device can be used on adults patients.
- The device must not be used as a physiological monitoring of vital signs.

7. TABULAR COMPARISON WITH PREDICATE DEVICES

Below the comparison table between CARDIOLINE touchECG, Mortara Rscribe Electrocardiograph and Mindray Passport 17m (12m)

FEATURES	CARDIOLINE touchECG	Mortara Rscribe Electrocardiograph	Shenzhen Mindray Bio-medical Electronics Co., Ltd - Passport Series Patient Monitors
Indication for use	touchECG is designed to check and diagnose cardiac function. However, a physician must validate the results of the analysis run by the ECG. touchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use by health professional in emergencies (ambulances). touchECG is intended to be used in conjunction with CARDIOLINE HD+ device. - The device analyzes, displays and prints out electrocardiograms. The ECG's are acquired from CARDIOLINE HD+ device. - The device interprets the data for review by a physician. - The device must be used by a physician or by health professionals on behalf of an authorized doctor in clinical facilities. It is not intended as the only means for determining the diagnosis. - The device's interpretation of the ECG analysis is only significant if used together with an additional analysis by the physician and by an assessment of all the patient's important data. - The device can be used on adults patients. - The device must not be used as a physiological monitoring of vital signs	The proposed Mortara RScribe Electrocardiograph is a non-invasive prescription device. - The device is indicated for use to acquire, analyze, display, transmit and print electrocardiograms. - The device is indicated for use to provide interpretation of the data for; consideration by a physician. - The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. - The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. - The device is indicated for use on adult and pediatric populations. - The device is not intended to be used as a vital signs physiological monitor. - The device is not designed for out of hospital transport. - The device is not designed for use in highly invasive environments, such as an operating	Passport 12m and 17m Patient Monitors: The Passport 17m and Passport 12m patient monitors are intended for monitoring, displaying, reviewing, alarming, and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), pulmonary artery wedge pressure (PAWP), cardiac output (C.O.), continuous cardiac output (CCO), mixed/central venous oxygen saturation (SvO2/ScvO2), carbon dioxide (CO2), Oxygen (O2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS), and respiration mechanics (RM). The equipment also provides an interpretation of resting 12-lead ECG. All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following: • The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO2/ScvO2, and PAWP monitoring are intended for adult and pediatric patients only; • ST Segment analysis of Mindray algorithm is intended for adult patients only; • C.O. monitoring is restricted to adult patients only; • ICG monitoring is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg. The monitor is to be used in healthcare facilities by clinical

		theatre.	professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.
Accessory	CARDIOILINE HD+ K150289	MORTARA WAM (Wireless Acquisition Module) or Mortara Acquisition Module (AM1 2) patient cables.	T1 Transport Monitor/ Module as a multi-parameter Module
Target population	Adults	Adults and Pediatric	Adults, pediatric, and neonatal
Safety standards	IEC 60601-2-25	Not specified	IEC 60601-1, IEC 60601-2-25
Sampling Rate	500 samples/second/channel	40,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis	500 samples/s (ECG algorithm)
Standard Leads which can be analyzed	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 to V6
A/D Conversion	Provided by auxiliary HD+ see table below	Not specified	500 samples/s (A/D)
Frequence responce	0.05 – 150 Hz	0.05 – 300 Hz	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz ST mode: 0.05 to 40 Hz
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011	Not specified	IEC 60601-2-25
Data transfer	Bluetooth 2.0+ with “secure pairing” using external hardware	Wireless	Not provided in Passport 17m device Wi Fi in Passport 12m device
Operating system	touchECG can be installed on a PC/TABLET/NOTEBOOK with Windows 7, Windows 8.1, Windows 10	Window 7 professional 32 or 64 bits	Proprietary system
Lead-fail detection	Independent for all leads	Not specified	Not specified
Cardiac frequency range	30 - 300 bpm	Not specified	15 – 350 bpm
ECG measurements	All leads, medians, corrected	Simultaneous acquisition of all 12 leads	Simultaneous acquisition of 3, 5, 12 leads
ECG acquisition mode	Automatic (12 leads), Manual (3/6 leads), Review (12 leads)	Not specified	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 12-lead: I, II, III, aVR, aVL, aVF, V1 to V6
Lead	Standard, Cabrera	Standard or Cabrera	Standard or Cabrera

configuration			
ECG interpretation	Glasgow algorithm for adults, STEMI (included in Glasgow algorithm)	Mortara VERITAS resting ECG interpretation algorithm with age and gender specific criteria; connectivity with bidirectional communication	Diagnostic 12-Lead ECG. Interpretation with Glasgow Algorithm
Exported formats	SCP-PDF-GDT: Standard format HL7: Optional	Experience the benefits of bidirectional communication with third party systems including EMR, HIS, and PACS via XML, PDF, and DICOM®. RScribe 5 also integrates with Athena, Mortara's multi-modality report repository, enabling convenient storage of ECG data.	HL7 export
Printing	Variable in relation to printer Format: A4 Sensitivity: 5, 10, 20 mV/mm Automatic print speed: 25, 50 mm/s Automatic print: 3, 3+1, 6, 12 channels; Standard or Cabrera; Automatic print formats: 12x1, 6x2, 3x4, 3x4+1, 3x4+3 Manual print speed: 5, 10, 25, 50 mm/sec Manual printing: 3, 6, 12 channels; Standard or Cabrera; Manual print formats: 12x1, 6+6, 3x1 Letter paper	HP 2055DN or HP Enterprise M601 with HPUPD PCL 5 driver or equivalent	Paper: A4, Letter

FEATURES RELATED TO CARDIOLINE HD+, the accessory which is intended to be used in conjunction with the subject device touchECG

FEATURES	**CARDIOLINE HD+**	**Mortara Rscribe Electrocardiograph**	**Shenzhen Mindray Bio-medical Electronics Co., Ltd - Passport Series Patient Monitors**
Accessory of subject device	CARDIOILINE HD+ K150289	MORTARA WAM (Wireless Acquisition Module) or Mortara Acquisition Module (AM1 2) patient cables.	T1 Transport Monitor/ Module as a multi-parameter Module
Target population	Adults	Adults and Pediatric	Adults, pediatric, and neonatal
Safety standards	IEC 60601-2-25	Not specified	IEC 60601-1, IEC 60601-2-25
ECG Leads	12-leads (I, II, III, aVR-L-F, V1-6)	12-leads (I, II, III, aVR, aVL, aVF, V1,V2,V3,V4,V5,V6)	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 12-lead: I, II, III, aVR, aVL, aVF, V1 to V6
Sampling Rate	500 samples/second/channel	40,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis	500 samples/s (ECG algorithm)

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 to V6
A/D Conversion	Not provided by software touchECG. Provided by auxiliary HD+ device:24 bit, 32 KHz	Not specified	500 samples/s (A/D)
Frequence responce	0.05 – 150 Hz	0.05 – 300 Hz	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz ST mode: 0.05 to 40 Hz
Defibrillator Protection	AAMI/IEC standard	Not specified	AHA, IEC
Pacemaker detection	Hardware detection coupled with digital convolution filter	Hardware detection	Present
Mains Power Supply	Battery operated	100 – 240 VAC at 50/60 Hz	100 to 240 VAC, 50/60 Hz 2 batteries 11.1 Vdc, 4500 mAh
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011	Not specified	IEC 60601-2-25
Data transfer	Bluetooth 2.0+ with “secure pairing”	Wireless	Not provided in Passport 17m device Wi Fi in Passport 12m device
Lead-fail detection	Independent for all leads	Not specified	Not specified
Cardiac frequency range	30 - 300 bpm	Not specified	15 – 350 bpm
AC filter	Adaptive 50/60 Hz digital filter	40 Hz and 150 Hz noise filters;	50/60 Hz Monitor, ST and surgical mode: Notch turns on automatically. Diagnostic mode: Notch is turned on/off manually
ECG measurements	All leads, medians, corrected	Simultaneous acquisition of all 12 leads	Simultaneous acquisition of 3, 5, 12 leads
ECG acquisition mode	Automatic (12 leads), Manual (3/6 leads), Review (12 leads)	Not specified	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 12-lead: I, II, III, aVR, aVL, aVF, V1 to V6
Lead configuration	Standard, Cabrera	Standard or Cabrera	Standard or Cabrera

8. PERFORMANCE DATA

Performance test are performed following the standard IEC 60601-2-25. These declared performances are applied to the software touchECG because this device is intended to be used in conjunction with the device Cardioline HD+ (K150289) to execute functions stated in the intended use of touchECG.

Then the ECG performances are to be verified and validated also for the software device touchECG using the combination of HD+ and touchECG to verify the performances of the touchECG software.

All the performances are verified also by printing the screenshot taked by the touchECG. All these screenshot are present in the file 031_510_TR_PR_TouchECG3_1402_00_eng_attachments_cardioline_touchECG.PDF and the explanation of all printed test is present on file 536_IEC60601-2-25_results_performances_list, both attached to the submission. The performance tested tests were passed regarding:

- Defibrillation Protection
- Overload Tolerance
- Requirements for amplitude measurements
- Interval Measurements
- Requirements for interval measurements on biological ECGs
- Indication of Inoperable ECG
- Leads
- Minimum Lead Configuration
- Wilson Leads
- Input Impedance
- Required Gains
- Common Mode Rejection
- Line Filter Response
- Noise Level
- Channel Crosstalk
- High Frequency Response
- Low Frequency Response
- Linearity and Dynamic Range
- Sampling and Amplitude Quantization
- Record Identification
- Patient Identification
- Recording Speed
- Time and Amplitude Ruling
- Use with Cardiac Pacemakers

9. CONCLUSION

The performance of touchECG are basically similar to the predicate and are summarized in table above. Like Mortara RScribe, the subject device touchECG, has the same hardware/software architecture: the ECG acquisition is on the acquisition module (HD+ for touchECG and WAM or AM12 for RScribe), interpretation is on board of the software on the PC (or notebook and tablet for CARDIOLINE touchECG). The interpretation algorithm is the same used in the predicate device Mindray Passport Series, the Glasgow Interpretation algorithm.

touchECG has similar wireless communication method between the interpreter and the acquirer of the Mortara Rscribe

touchECG has the same interpretation algorithm of Mindray Passport Series, the Glasgow Interpretation algorithm.

The Standards Leads Acquired are the same for touchECG and both predicates devices.

The intended use of CARDIOLINE touchECG is the same of Mortara RScribe.

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. touchECG is a complete electrocardiograph with the acquisition device and with an analysis, diagnosis and monitoring features.