



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 12, 2016

Cardioline S.p.A
Mr. Alessandro Peluso
Official Correspondent
Via Prati 1/2
Zola Predosa-localita Ponte Ronca-bologna, 40069 IT

Re: K160840
Trade/Device Name: ECG100+, ECG200+
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: March 11, 2016
Received: April 6, 2016

Dear Mr. 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,



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)
K160840

Device Name
ECG100+, ECG200+

Indications for Use (Describe)

ECGxxx(z)(+) is a high-performance, multi-channel, interpretative resting electrocardiograph.

The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.

ECGxxx(z)(+) is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and doctor's offices of any size.

- The device is indicated for use to acquire, analyse, display and print electrocardiograms.
- The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed 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.

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 ECGxxx(z)(+)**1. SUBMITTER**

CARDIOLINE S.p.A
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F +39 0463 850088

Contact Person: Mr Emanuele Ercoli
Date prepared: September 15, 2015

2. DEVICE

Name of Device: Cardioline ECGxxx(z)(+)
Common or Usual Name: ECGxxx(z)(+) Electrocardiograph
Model name: ECG100+, ECG200+
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.	ET MEDICAL DEVICES SPA	K051534
Cardioline S.p.A.	Cardioline S.p.A.	MORTARA INSTRUMENTS INC.	K101403

4. DEVICE DESCRIPTION

ECGxxx(z)(+) is a family of high-performance, multi-channel, interpretative resting electrocardiograph. ECG100+ and ECG200+ are two models of that electrocardiographs family.

The device is a 12-lead diagnostic electrocardiograph which displays, acquires, prints and stores ECG tracings for adults and children. It also calculates the main overall ECG parameters.

The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm can provide an over-reading physician with a second opinion generating diagnostic messages in the ECG report.

For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list)

The device can be configured with a larger memory, with bidirectional connectivity (LAN) and with DICOM® functionality.

The device can be powered by battery or the electrical mains.

The printing formats supported include: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channels in automatic mode and 3, 6 or 12 (only for ECG200+) channels rhythm strip printing.

The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyze and store the ECG traces, send them to an external peripheral via network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.

ECGxxx(z)(+) is intended for control and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Cardiologist.

ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and offices of any size.

ECGxxx(z)(+) is a family of electrocardiographs which are a 12-lead diagnostic electrocardiographs and which are intended to displays, acquires, prints and stores ECG tracings for adults and children. It also calculates the main overall ECG parameters.

The devices have the following characteristics:

- mains and internal battery operation
- manual and automatic acquisition of the 12 Standards Leads
- simultaneous acquisition of the 12 Standards Leads
- internal storage up to 100 ECGs. Can storage up to 1000 ECGs optionally
- multichannel ECG printout on thermal paper:
 - a) (for ECG100+) 3, 6 channels, 5/10/25/50 mm/s
 - b) (for ECG200+) 3, 6 or 12 channels, 5/10/25/50 mm/s
- high resolution thermal printer:
 - a) (for ECG100+) 8 dot/mm - 108mm; Z-fold 100x150mm
 - b) (for ECG200+) 8 dot/mm - 216mm; A4 Z-fold
- for autoprint mode:
 - a) (for ECG100+) Standard or Cabrera; 3, 3+1, 6 channels Patient Demographic, Global Measurements, Optional Interpretation (Glasgow University - Prof. MacFarlane) Adult, Paediatric, STEMI
 - b) (for ECG200+) Standard or Cabrera; 3, 3+1, 6, 12 channels Patient Demographic, Global Measurements, Optional Interpretation (Glasgow University - Prof. MacFarlane) Adult, Pediatric, STEMI
- display:
 - a) (for ECG100+) Backlit, colour LCD display, 4.3" ECG waveform real-time tracing
 - b) (for ECG200+) 7" backlit LCD colour display, displays the ECG waves in real time
- Keyboard (for both devices): Mechanical keypad with alphanumeric keys and special function keys
- filters (for both devices): diagnostic fully digital high pass filter; adaptive digital AC interference filter (50/60 Hz); digital low pass filter muscular filter 25 and 40 Hz (only for display and printing)
- connectivity (for both devices): USB device and LAN (optional)
- patient cable (for both devices): standard 15D, 10-wires
- Data export (for both devices): SCP (standard format), XML-PDF-GDT (included in standard connectivity option), DICOM (included in DICOM connectivity option), HL7 (optional).

More specifically, the equipment family is based on two model variants characterized by different print and display capabilities.

Both devices offers full ECG acquisition meeting the standards used in clinical and diagnostic applications (AAMI, ANSI, AHA, ACC). When battery powered both devices have a duration of more than 500 ECGs and the recharging time is 4 hours to 85% of full charge.

The package includes (for both devices):

1. Patient cable
2. AC Power supply (100-240 VAC 50/60 Hz)
3. Paper
4. Pack of electrodes
5. Banana/clip adapter set
6. Guidance for the physician on the application on adults and children (with interpretative key)
7. User manual

The common family name is ECGxxx(z)(+). Where:

xxx = printer size

+ = model with network connectivity

z = models with different interfaces

(refer to Technical File for more details)

The results of the analysis must always be validated by qualified, trained medical personnel and the devices are intended for use in a medical environment. ECG100+ and ECG200+ are intended to be used on adult and all pediatric patients. The devices 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

ECGxxx(z)(+) is a high-performance, multi-channel, interpretative resting electrocardiograph.

The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.

ECGxxx(z)(+) is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and doctor's offices of any size.

- The device is indicated for use to acquire, analyse, display and print electrocardiograms.
- The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed 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.

6. TABULAR COMPARISON WITH PREDICATE DEVICES

For the comparison below, are present two tables:

TABLE 1: the ECG100+ is compared with AR 1200 of ET MEDICAL and ELI 250 of MORTARA INSTRUMENTS INC.

TABLE 2: the ECG200+ is compared with AR 2100 of ET MEDICA and ELI 250 of MORTARA INSTRUMENTS INC.

Table 1

FEATURES	CARDIOLINE ECG100+	AR 1200	ELI 250
Indication for use	<p>ECGxxx(z)(+) is a high-performance, multi-channel, interpretative resting electrocardiograph.</p> <p>The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.</p> <p>ECGxxx(z)(+) is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.</p> <p>ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and doctor's offices of any size.</p> <ul style="list-style-type: none"> - The device is indicated for use to acquire, analyse, display and print electrocardiograms. - The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed 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 	<p>CARDIOLINE AR 600 and AR 1200 and AR 2100 are a family of electrocardiograph recorders provided with a program for automated ecg analysis and with a graphic LCD display.</p> <p>The equipments are intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and is recorded on thermal paper.</p> <p>Intended use for non interpretive applications covers the full range of patient population with no limitations with respect to age, sex and race of the patient.</p> <p>The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rhythm and morphology.</p> <p>Interpretation Statements must be overviewed and approved by trained Physician's. Interpretation statements just represent a partial qualitative and quantitative information of the general patient cardiovascular condition: no therapy or drugs can be subministrated based solely on Interpretation statements.</p> <p>The equipments are intended to be used by trained medical personnel or physician's.</p> <p>Indication for use of the modified device has not been changed with respect to the predicate device AB CARDIETTE DAEDALUS VIEW base and Hes K002074.</p>	<ul style="list-style-type: none"> - The device is indicated for use to acquire, analyze, display 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 EGG 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

	<p>well as consideration of all other relevant patient data.</p> <ul style="list-style-type: none"> - 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. 		
Target population	Adults and pediatric patients Adults and pediatric patients for analysis	Adults and pediatric patients Adults for analysis	Adults and pediatric patients Adults and pediatric patients for analysis
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
ECG Leads	12 Leads Standard / Cabrera	12 Leads Standard / Cabrera	12 Leads Standard / Cabrera
Sampling Rate	500 samples/second/channel	1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters	1000 s/sec/channel used for recording and analysis
Leads Connector	Single block	Single block	Single block
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, 32 KHz	12 bit	20 bit
Bandwidth	0.05 – 150 Hz	0,05 – 150 Hz	0.05Hz – 300Hz
CMRR	>100 dB	>100 dB	Not specified
Defibrillator Protection	AAMI/IEC standards	AAMI/IEC standards with proprietary applied part	Defibrillation proof applied part
Pacemaker detection	Hardware detection coupled with convolution digital filtering	Recognize pacemaker impulse according to IEC applicable standards	Not specified
Patient Cable	10 wire single connector	10 wire single connector	10 wire cable single connector
Mains Power Supply	Medical grade AC power supply (100-240 VAC, 50/60 Hz);	Internal power supply 90-264 VAC, 47 – 63 Hz	Universal AC power supply (100-240 VAC at 50/60 Hz) 50 VA
Internal battery	Internal rechargeable battery (NiMH), 12Vdc 2200 mAh	Rechargeable battery pack NiMH 10x1.2 Vdc; 1800 mAh	Internal rechargeable battery
Writing system	Thermal head, 8 dot/mm - 108mm; Z-fold 100x150mm	Thermal head 108mm 8 dots/mm	Computer-controlled dot array; 1 dot/ms horizontal, 8 dots/mm vertical
Printed channels	Manual: 3, 6 channels Automatic: 3, 3+1, 6 channels, Patient Demographic, Global Measurements, Optional Interpretation (Glasgow University – Prof. MacFarlane) Adult, Paediatric, STEMI	3/4/6 channels	3, 6 or 12 channel with configurable lead groups
Paper speed	5/10/25/50 mm/s	5 mm/s ±10% 25 – 50 mm/s ±5%	5, 10, 25, or 50 mm/s
Paper type	Z-FOLD 100X150	DOTCARD 120mm	Perforated Z-fold thermal paper, A4 or 8.5 x 11" wide, 250 sheets
Mode of operation	Manual and automatic	Manual and automatic recording	Automatic
Display	Size: 4.3" colour LCD monitor N° of displayed channels: 3, 6 Traces speed: 50/25/10/ 5 mm/sec	Size: 120 x 320 pixels / 240 x 320 pixels N° of displayed channels: 3, 6, 12 Traces speed: 12,5 / 25 / 50 mm/sec	Size: Backlit, 1/4 VGA color LCD (320 x 240) N° of displayed channels: 3, 4, 6 Traces speed: not specified
Connectivity	USB device, LAN	Infrared digital interface	RS232, LAN, WLAN, Modem
ECG	Glasgow resting ECG	Hannover ECG System (HES)	Mortara VERITAS resting

interpretation	interpretation algorithm (adult and pediatric) [optional]	interpretation program	interpretation algorithm (adult and pediatric) [optional]
Where used Used By	Hospitals, Medical Clinics. Nurse, Physician and trained medical personnel	Hospitals, Clinics Physician and trained medical personnel	Hospitals, Clinics Physician and trained medical personnel

Table 2

FEATURES	CARDIOLINE ECG200+	AR 2100	ELI 250
Indication for use	<p>ECGxxx(z)(+) is a high-performance, multi-channel, interpretative resting electrocardiograph. The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.</p> <p>ECGxxx(z)(+) is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.</p> <p>ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and doctor's offices of any size.</p> <ul style="list-style-type: none"> - The device is indicated for use to acquire, analyse, display and print electrocardiograms. - The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed 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 	<p>CARDIOLINE AR 600 and AR 1200 and AR 2100 are a family of electrocardiograph recorders provided with a program for automated ecg analysis and with a graphic LCD display.</p> <p>The equipments are intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and is recorded on thermal paper.</p> <p>Intended use for non interpretive applications covers the full range of patient population with no limitations with respect to age, sex and race of the patient.</p> <p>The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rhythm and morphology.</p> <p>Interpretation Statements must be overviewed and approved by trained Physician's. Interpretation statements just represent a partial qualitative and quantitative information of the general patient cardiovascular condition: no therapy or drugs can be subministrated based solely on Interpretation statements.</p> <p>The equipments are intended to be used by trained medical personnel or physician's.</p> <p>Indication for use of the modified device has not been changed with respect to the predicate device AB CARDIETTE DAEDALUS VIEW base and Hes K002074.</p>	<ul style="list-style-type: none"> - The device is indicated for use to acquire, analyze, display 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 EGG 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

	<p>conjunction with a physician over-read as well as consideration of all other relevant patient data.</p> <ul style="list-style-type: none"> - 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. 		
Target population	Adults and pediatric patients Adults and pediatric patients for analysis	Adults and pediatric patients Adults for analysis	Adults and pediatric patients Adults and pediatric patients for analysis
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
ECG Leads	12 Leads Standard / Cabrera	12 Leads Standard / Cabrera	12 Leads Standard / Cabrera
Sampling Rate	500 samples/second/channel	1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters	1000 s/sec/channel used for recording and analysis
Leads Connector	Single block	Single block	Single block
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, 32 KHz	12 bit	20 bit
Bandwidth	0.05 – 150 Hz	0,05 – 150 Hz	0.05Hz – 300Hz
CMRR	>100 dB	>100 dB	Not specified
Defibrillator Protection	AAMI/IEC standards	AAMI/IEC standards with proprietary applied part	Defibrillation proof applied part
Pacemaker detection	Hardware detection coupled with convolution digital filtering	Recognize pacemaker impulse according to IEC applicable standards	Not specified
Patient Cable	10 wire single connector	10 wire single connector	10 wire cable single connector
Mains Power Supply	Medical grade AC power supply (100-240 VAC, 50/60 Hz);	Internal power supply 90-264 VAC, 47 – 63 Hz	Universal AC power supply (100-240 VAC at 50/60 Hz) 50 VA
Internal battery	Internal rechargeable battery (NiMH), 12Vdc 2200 mAh	Rechargeable battery pack NiMH 10x1.2 Vdc; 1800 mAh	Internal rechargeable battery
Writing system	Thermal head, 8 dot/mm - 216mm; A4 Z-fold	Thermal head 210mm 8 dots/mm	Computer-controlled dot array; 1 dot/ms horizontal, 8 dots/mm vertical
Printed channels	Manual: 3, 6, 12 channels Automatic: 3, 3+1, 6, 12 channels Patient Demographic, Global Measurements, Optional Interpretation (Glasgow University – Prof. MacFarlane) Adult, Paediatric, STEMI	3/4/6/12 channels	3, 6 or 12 channel with configurable lead groups
Paper speed	5/10/25/50 mm/s	5 mm/s ±10% 25 – 50 mm/s ±5%	5, 10, 25, or 50 mm/s
Paper type	A4 Z-fold	DOTCARD 210mm	Perforated Z-fold thermal paper, A4 or 8.5 x 11" wide, 250 sheets
Mode of operation	Manual and automatic	Manual and automatic recording	Automatic
Display	Size: 7" backlit LCD colour display	Size: 120 x 320 pixels / 240 x 320	Size: Backlit, 1/4 VGA color LCD

	N° of displayed channels: 3, 6, 12 Traces speed: 50/25/10/ 5 mm/sec	pixels N° of displayed channels: 3, 6, 12 Traces speed: 12,5 / 25 / 50 mm/sec	(320 x 240) N° of displayed channels: 3, 4, 6 Traces speed: not specified
Connectivity	USB device, LAN	Infrared digital interface	RS232, LAN, WLAN, Modem
ECG interpretation	Glasgow resting ECG interpretation algorithm (adult and pediatric) [optional]	Hannover ECG System (HES) interpretation program	Mortara VERITAS resting interpretation algorithm (adult and pediatric) [optional]
Where used Used By	Hospitals, Medical Clinics. Nurse, Physician and trained medical personnel	Hospitals, Clinics Physician and trained medical personnel	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 test have shown full compliance with these device.

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.

Performance are tested following the standard IEC 60601-2-25 second edition.

The performance tested are:

- Defibrillation protection
- Energy reduction test
- Overload tolerance
- Indication of inoperable electrocardiograph
- LEAD representation, nomenclature and definition
- Goldberg and Wilson LEADS
- Recovery time
- Input impedance
- Common mode rejection
- Filters
- Noise level
- Channel crosstalk
- High frequency response
- Low frequency (impulse) response
- Linearity and dynamic range
- Recording speed
- Time and amplitude ruling
- Use with cardiac pacemakers

8. CONCLUSION

The safety features of the **CARDIOLINE ECGxxx(z)(+)** are identical to those of the predicate devices ET MEDICAL CARDIOLINE AR and MORTARA ELI 250.

The performance of ECGxxx(z)(+) are basically similar to the predicate and are summarized in table above. Like predicate devices CARDIOLINE AR, the subject devices ECGxxx(z)(+), have parameters computation and interpretation program implemented on device and uses the same paper format.

Like Mortara ELI 250, is designed to acquire and analyze ECG data for pediatric populations. Like Mortara ELI 250 has the network connectivity.

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

The intended use of CARDIOLINE ECGxxx(z)(+) is the same both devices

The conclusions drawn from the nonclinical and clinical tests demonstrates 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.