5. Summary of Safety and Effectiveness

CARDIOLINE AR 600, AR 1200, AR 2100

5.1 Date of application: 06/07/2005

5.2 Applicant's name and address: et medical devices spa
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5.3 Contact person: Mr. Attilio Castelli
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5.4 Device Trade Name
CARDIOLINE AR 600, AR 1200, AR 2100

5.5 Device Common Name
ECG Interpretive Electrocardiograph

5.6 Device Classification Name
CFR 870.2340 Electrocardiograph Class II 74 DPS

5.7 Unmodified (Predicate) Device
The legally marketed device which has been modified is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
Elettronica Trentina spa (*)	H&C Medical Devices spa (°)	AB CARDIETTE Daedalus View base and Hes	**K002074**

(*) name changed into et medical devices spa in year 2003.
(°) merged into et medical devices spa in year 2003.

The safety features of the CARDIOLINE AR 600, AR 1200 and AR 2100 are identical to those of the predicate Daedalus View. The performances of CARDIOLINE AR 600, AR 1200 and AR 2100 are basically similar to the predicate Daedalus View and are summarized in **table 5.7.1**. The Parameters computation and Interpretation Program implemented in CARDIOLINE AR 600 and AR 1200 and AR 2100 is equivalent to the one implemented in the predicate Daedalus View Hes.

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Summary of Safety and Effectiveness (con't)

Intended use of CARDIOLINE AR 600 and AR 1200 and AR 2100 is identical to that of AB CARDIETTE Daedalus View base and Hes.

Table 5.7.1

Parameter	AR 600	AR 1200	AR 2100	AB CARDIETTE DAEDALUS VIEW Base and Hes
RECORDER				
Input dynamic range	+/-300mV @ DC +/- 5.0 mV within the bandpass	+/-300mV @ DC +/- 10.0 mV within the bandpass	+/-300mV @ DC +/- 10.0 mV within the bandpass	+/-300mV @ DC +/- 25 mV within the bandpass
Frequency response	0.05 – 150 Hz (-3dB)	0.05 – 150 Hz (-3dB)	0.05 – 150 Hz (-3dB)	0.05 – 150 Hz (-3dB)
A/D conversion	11 bits	12 bits	12 bits	14 bits
Leads	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera
Sensitivity	2.5 5 10 20 mm/mV +/-5%	2.5 5 10 20 mm/mV +/-5%	2.5 5 10 20 mm/mV +/-5%	1.25 2.5 5 10 20 40 mm/mV +/-5%
Writing system	Thermal head 48 mm 8 dots/mm	Thermal head 108 mm 8 dots/mm	Thermal head 210 mm 8 dots/mm	Thermal head 210 mm 8 dots/mm
Printed channels	1/2/3	3/4/6	3/4/6/12	3/4/6/12
Paper speed	25 50mm/s +/-5%	5 mm/s +/-10% 25 50mm/s +/-5%	5 mm/s +/-10% 25 50mm/s +/-5%	1.25 2.5 5 10 12.5 mm/s +/-10% 25 50mm/s +/-5%
Thermal paper	DOTCARD 65 mm	DOTCARD 120 mm	DOTCARD 210 mm	DOTCARD 210 mm
Mode of operation	Manual and Automatic recording	Manual and Automatic recording	Manual and Automatic recording	Manual, Manual delayed and Automatic recording
Input/output	Infrared digital interface	Infrared digital interface	Infrared digital interface	RS 232 standard digital port
DISPLAY				
Size	120 x 32 pixels	120 x 32 pixels / 240 x 320 pixels	120 x 32 pixels / 240 x 320 pixels	VGA 640 x 480 pixels
N° of displayed channels	none	3/6	3/6/12	3/6
Traces speed	N/a	12.5 25 50 mm/s	12.5 25 50 mm/s	1.25 2.5 5 10 12.5 25 50 mm/s
Sensitivity	N/a	5 10 20 mm/mV	5 10 20 mm/mV	1.25 2.5 5 10 20 40 mm/mV

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5.8 Device description

CARDIOLINE AR 600, AR 1200 and AR 2100 is a family of electrocardiographs providing the following characteristics:

- Mains and internal battery operation
- Manual acquisition of the 12 Standard Leads
- Simultaneous acquisition of the 12 Standard Leads
- Storage of 10 seconds of acquired ecg signal
- Storage of up to 40 ecg recordings (optional)
- Multichannel Ecg printout on thermal paper
- Copy function of the stored ecg
- High resolution digital thermal printer
- Digital filters for AC interference suppression and base-line drift
- Time and date printout
- Possibility to send acquisition data to a Personal Computer or Workstation via Infrared serial interface
- Interpretation Program Hannover Ecg System (HES) providing the following additional informations (optional):
  - Representatives Templates of each lead including markers on fiducial points
  - Summary of mean measurements
  - Summary of measurements performed on each lead
  - Rythm Analysys Statements
  - Rythm graphical representation
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements
  - QRS T Diagnostic Statements
  - Summary of measurements performed on each lead
  - Arrhythmia monitoring detection
  - Heart Rate Variability
- graphic LCD display for user interface and ECG visualisation
- Patient input data for Interpretation, identification and filing purposes

More specifically, the equipments family is based on 3 model variants characterized by different print and display capabilities. Table 5.8.1 summarizes all model variants.

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Table 5.8.1

Model variant	Thermal head	LCD display	Interpretation
AR 600	50 mm	YES (alpha-num.)	YES
AR 1200	108 mm	YES (graphic)	YES
AR 2100	210 mm	YES (graphic)	YES

5.9 Intended use

CARDIOLINE AR 600, AR 1200 and AR 2100 is a family of electrocardiographs characterized as basic standard electrocardiographs with program for automated ecg analysis.

Intended use is equivalent to the intended use of the predicate Daedalus View. More specifically:
The equipment 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 can be visualized on a digital display and recorded on thermal paper.

Intended use for non interpretive applications covers the full range of patient population with no limitiations with respect to age, sex and race of the patient.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rythm and morphology.

5.10 Comparison of technological characteristics

CARDIOLINE AR 600 and AR 1200 and AR 2100 electrocardiographs are based on the same technological characteristics of the predicate device AB CARDIETTE Daedalus View base and Hes.

5.11 Non clinical tests used for Substantial Equivalence Determination

Full safety tests according to EN60601-1 and IEC 601-2 25 have been performed on all model variants. Tests have shown full compliance with these standards.
The equipments have been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard. Tests have shown full compliance with this standard.
The correct implementation of the measurements and interpretation program has also been tested and validated.
The measurements and interpretation program has not been changed. It has been intensively tested and validated by the developer Medizinische Hochschule

Hannover. Test results have been published on the New England Journal of Medecine 325:1767-1773 December 19, 1991 under the title:
The Diagnostic Performance of Computer Programs for the Interpretation of Electrocardiograms.
The results shown in this study have demonstrated the quality and accuracy of the HES program with respect to other commercially availabe programs.
Moreover, the equipments are marketed worldwide since 2001 under the name CARDIETTE AR 600, AR 600 ADV, and AR 1200 ADV, AR 1200 VIEW, AR 2100, AR 2100 VIEW.
No adverse working conditions have been claimed and filed up to date.
All equipments are CE marked according to 93/42/CEE Medical Device Directive.

5.12 Risk Analysis
Comparative risk analysis has been performed with respect to the umodified (predicate) device (see Att. **A**) demonstrating that all means adopted for risk reduction were identical to those adopted for the umodified equipment. The safety and the risk related to the use of the modified equipment are identical to the unmodified equipment.

5.13 Conclusions
Based on the above, et medicale devices belives that CARDIOLINE AR 600, AR1200 and AR 2100 electrocardiographs are substantially equivalent to AB CARDIETTE Daedalus View base and Hes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2005

et medical devices SpA
c/o Mr. Attilio Castelli
Via De Zinis, 6
38011 Cavareno (TN)
ITALY

Re: K051534
Trade Name: Cardioline AR 600, AR 1200 and AR 2100
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: August 31, 2005
Received: September 6, 2005

Dear Mr. Castelli:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

et medical devices spa

Indications for Use:

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.

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.

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.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rhythm and morphology.

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.

The equipments are intended to be used by trained medical personnel or physician's.

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.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051534