5. Summary of Safety and Effectiveness

FEB 19 2009

cardiette microtel

5.1 Date of application

10/07/2008

5.2 Applicant's name and address

et medical devices spa
Via De Zinis 6
38011 Cavareno
(Trento) ITALY

5.3 Contact person

Mr. Luigi Bucchi
Tel: (+39) 02 95051854
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5.4 Device Trade Name

cardiette microtel

5.5 Device Common Name

Electrocardiograph

5.6 Device Classification Name

CFR 870.2340 Electrocardiograph
Class II 74DPS

5.7 Unmodified (Predicate) Device

The legally marketed device which has been modified is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
et medical devices SpA	et medical devices SpA	CARDIOLINE AR 600, AR 1200 and AR 2100	**K051534**

The safety features of the **cardiette microtel** are identical to those of the predicate CARDIOLINE AR 600, AR 1200 and AR 2100. The performance of **cardiette microtel** are basically similar to the predicate CARDIOLINE AR 600, AR 1200 and AR 2100 and are summarized in **table 5.7.1**. The **cardiette microtel** is not equipped with the Parameters computation and Interpretation Program implemented in CARDIOLINE AR 600 and AR 1200 and AR 2100.
Intended use of **cardiette microtel** is identical to that of CARDIOLINE AR 600 and AR 1200 and AR 2100 excluding the Parameters computation and Interpretation Program.

5.7.1. Table - Cardiette Microtel in comparison with AR600 (Predicate Device)

Parameter RECORDER	MICROTEL	AR 600	AR 1200	AR 2100
ECG Signals				
Input dynamic range	+/-300mV @ DC +/- 5.0 mV within the bandpass	+/-300mV @ DC +/- 5.0 mV within the bandpass	+/-300mV @ DC +/- 10.0 mV within the bandpass	+/-300mV @ DC +/- 10.0 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	11 bits	12 bits	12 bits
Leads	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera
Sensitivity (LSB)	5 µvolts (microvolt)	5 µvolts (microvolt)	5 µvolts (microvolt)	5 µvolts (microvolt)
Writing system				
Writing system	Not present	Thermal head 48 mm 8 dots/mm	Thermal head 108 mm 8 dots/mm	Thermal head 210 mm 8 dots/mm
Printed channels	Not applicable	1/2/3	3/4/6	3/4/6/12
Paper speed	Not applicable	25 50mm/s +/-5%	5 mm/s +/-10% 25 50mm/s +/-5%	5 mm/s +/-10% 25 50mm/s +/-5%
Thermal paper	Not applicable	DOTCARD 65 mm	DOTCARD 120 mm	DOTCARD 210 mm
Mode of operation	Not applicable	Manual and Automatic recording	Manual and Automatic recording	Manual and Automatic recording
Interfaces				
Input/output	➢ Sound couple transmission ➢ USB (optional) ➢ Blue Tooth (only for microtel bt version).	Infrared digital interface	Infrared digital interface	Infrared digital interface
DISPLAY				
Size	Backlit single-colour LCD 128x64 pixels	None/120 x 32 pixels	120 x 32 pixels / 240 x 320 pixels	120 x 32 pixels / 240 x 320 pixels
N° of displayed channels	1	none	3/6	3/6/12
Traces speed	12,5 mm/s	N/a	12.5 25 50 mm/s	12.5 25 50 mm/s
Sensitivity	5 mm/mV	N/a	5 10 20 mm/mV	5 10 20 mm/mV
Keyboard				
Type / keys	Silicon rubber 20 functional keys	Membrane 21 functional keys	Membrane 46 functional keys	Membrane 49 functional keys
SW options				
ECG Interpretation	No	Interpretation Program HES EKG developed by the Medizinische Hochschule Hannover (Germany)	Interpretation Program HES EKG developed by the Medizinische Hochschule Hannover (Germany)	Interpretation Program HES EKG developed by the Medizinische Hochschule Hannover (Germany)

5.8 Device description

cardiette microtel is an electrocardiograph providing the following characteristics:

- standard and/or rechargeable internal AA batteries
- simultaneous acquisition and storage of the 12 standard leads acquired from a 10 wire cable, or 7 leads (6 peripheral + 1 precordial) acquired from a 5 wire cable.
- storege of 10 second ECG of acquired ECG signals (in 12 and 7 lead formats)
- storage of up to 40 ecg recordings (optional)
- digital filters for AC interference suppression and base-line drift
- transmition of the ECG in an analogue format via sound coupling or in digital format (SCP format) via the USB port and also via the wireless Bluetooth channel
- graphic LCD display for user interface and ECG visualisation (the ecg trace may be used only to evaluate the quality of the acquired ecg)
- functional keyboard for patient identification input data (disabled in the basic product), ECG recording and ECG sending operations

More information about the **cardiette microtel** device is available in the **Attachment A "Hardware and Software description"**.

5.9 Intended use

Intended use of **cardiette microtel** is equivalent to the intended use of the predicate CARDIOLINE AR 600, AR 1200 and AR 2100.
More specifically:
The equipment is 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. The ECG signals can be visualized on a digital display (this only to verify the quality of the signals). The acquired ecg can be send to a personal computer or other device able show it on a video and/or print the ecg signals on a printer or a paper thermal recorder.
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 equipment is intended to be used by trained medical personnel or physicians.

5.10 Comparison of technological characteristics

cardiette microtel electrocardiograph is based on the same technological characteristics of the predicate device CARDIOLINE AR 600 and AR 1200 and AR 2100. The differences between **cardiette microtel** electrocardiograph and the predicated device is that the **cardiette microtel** does not include the thermal printer and it is not equipped with the measurements and interpretation software program.

5.11 Non clinical tests used for Substantial Equivalence Determination

Full safety tests according to EN60601-1, IEC 601-2 25 and IEC 601-2-51 have been performed on the device, on both version of CARDIETTE MICROTEL (Standard and Bluetooth versions). Tests have shown full compliance with these standards.
The equipment has been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard. Tests have shown full compliance with this standard.
The Bluetooth version complies with ETSI EN 301 489-17 v 1.2.1 (2002-08) and ETSI EN 300 328 v 1.7.1 (2006-10) Standard concerning the radio equipment and telecommunications terminal equipment. Tests have shown full compliance with these standards.

In comparison with the predicate device CARDIOLINE AR 600 and AR 1200 and AR 2100, **cardiette microtel** has not the measurements and interpretation program.

Moreover, the previous model of **cardiette microtel**, the equipment Microtel and Microtel 232 that used respectively the acoustic and serial interface to transfer the ecg signals to a computer, are manufactured and marketed worldwide since 2002.
No adverse working conditions have been claimed and filed up to this date.
The equipment is CE marked according to 93/42/CEE Medical Device Directive.

5.12 Risk Analysis

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

5.13 Conclusions

Based on the above, et medical devices SpA believes that **cardiette microtel** electrocardiograph is substantially equivalent to CARDIOLINE AR 600, AR1200 and AR 2100.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2009

et medical devices SpA
c/o Mr. Luigi Bucchi
Quality Assurance Manager
Via De Zinis 6
Calvareno
Italy 38011

Re: K082124
Trade/Device Name: Cardiette Microtel
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: January 16, 2009
Received: January 21, 2009

Dear Mr. Bucchi:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): __ **K082124** __

Device Name: ___ **cardiette microtel** _____

Indications for Use:

cardiette microtel is a 12 lead ECG acquirer fitted with a display and keyboard.
The electrical heart activity is detected by means of two or more electrocardiograph electrodes and the device can acquire and transmit an ECG trace in analogue (via sound coupling) or digital format (USB port or via the wireless Bluetooth channel) to a remote PC.

The equipments are intended for use in routine ecg recording in physician practice and/or hospital.
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 equipment is intended to be used by trained medical personnel or physicians.

cardiette microtel does not include ecg interpretation tools and/or analysis programs. The device is intended to transmit ECG waveforms to a PC. Analysis program on a PC is a separate product not marketed with the Cardiette Microtel.

The hardware and the software of the equipment, except for the paper recorder routines and interpretation program, are the same of the predicated device.

Indication for use of cardiette microtel has not been changed, except for the ecg interpretation program not present on this device, with respect to the predicate device CARDIOLINE AR600, AR1200, AR2100 (ref. K051534 CARDIOLINE AR600, AR1200, AR2100).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 2/20/09
Division of Cardiovascular Devices
510(k) Number K082124