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6. 510(k) Summary

Date of application:

Applicant's name and address: Gem-Med S.L.
Calle Cartagena 245, 5é, of. 5-6
08025, Barcelona (Spain)

Contact Person: Mr. Wilson Tseng
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E-mail: wtseng@gem-med.com

Date of submission: December, 15th 2008

Device Trade Name: Gem Heart One/One+

Device Common Name: Electrocardiograph

Device Classification Name: CFR 870.2340 Electrocardiograph

Product Code: DPS Class II

Predicate Device	Premarket Notification
CARDIOLINE AR1200	K051534
CORSCREEN	K070614

Summary of Safety and Effectiveness

Parameter	Cardioline AR 1200	Gem Heat One	CorScreen
Input dynamic range	+/-300mV @ DC +/-10.0mV within the bandpass	+/-300mV @ DC +/-18.0mV within the band pass	+/-300mV @ DC
Frequency response	0.05-150Hz (-3dB)	0.05-150Hz	0.05-150Hz
A/D conversion	12 bits	16 bits	24 bits
Leads	12 Standard / 12 Cabrera	12 Standard / 12 Cabrera / 3+3 Orthogonal	12 Standard

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Sensitivity	2.5 5 10 20 mm/mV +/-5%	2.5 5 10 20 mm/mV	5, 10, 20 mm/mV
Writing system	Thermal head 108mm 8 dots/mm	Thermal head 110mm 16dots/mm – 8dots/mm	Ink Printer US letter and DIN-A4 size
Printed channels	3/4/6	1/3/6	1/2/6/12
Paper speed	5mm/s +/-10% 25 50mm/s +/-5%	10 25 50 mm/s	25 50 mm/s
Thermal paper	DOTCARD 120mm	DOTCARD 120mm	US letter and DIN-A4
Mode of operation	Manual and Automatic recording	Manual and Automatic recording	Manual
Input/output	Infrared digital interface	RS 232, Ethernet, USB,	SD Memory card
DISPLAY	AR 1200	Gem Heat One	Co Screen
Size	120x32 pixels / 240x320 pixels	240X320 pixels	240X320 pixels
Nº of displayed channels	3/6	1/3/6/12	1/3/6/12
Traces speed	12.5 25 50 mm/s	10 25 50 mm/s	5 10 25 50 mm/s
Sensitivity	5 10 20 mm/mV	2.5 5 10 20 mm/mV	5 10 20 40 mm/mV

Device description

The **Gem Heart One/One+** is a portable electrocardiograph of 12 channels with simultaneous leads recording, with a high quality thermal printing of 112 mm, a lithium ion battery, high resolution screen, and connectivity through serial port (RS-232), local network LAN (10/100 Base T) and USB 2.0.

The device includes protection against defibrillation integrated. Provides the automatic interpretation based on the program Hannover Ecg System HES® developed by Biosigna GmbH under the standards IEC 60601-2-51:2003. Uses the format SCP (Standard Communications Protocol) to import and export the ECG records in the framework of the CSE (Common Standards for Quantitative Electrocardiography) of the European Union.

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The Gem Heart One/One+ can operate in Spanish, Catalan and English and other languages can be implemented. It includes downloading and ECG viewing PC software gem heart viewer.

Intended use

Gem Heart One/One+ is a standard 12 leads electrocardiograph designed to register, analyze and display electrocardiograms at rest. It is capable of displaying up to 12 leads at a time on the screen and print 3/6 channels by means of its thermal printer of 112mm width.

It incorporates the Hannover Electrocardiogram System (HES) automatic interpretation program for cardiac signal analysis and has the possibility of introducing the patient's data, store the records and send them to a PC by serial communication (RS-232, USB and LAN). The interpretation by the Gem Heart One/One+ is only significant if it is considered and analysed by a qualified physician and used for patients over 16 years old. No therapy or drugs can be administered based solely on the interpretations statements obtained from the HES interpretation program.

For non-interpretative applications, the Gem Heart One/One+ can be used for patients with no limitations with respect to age, sex and race of the patient. It is intended for use in routine ECG recording by trained physicians in hospital environment.

- The Gem Heart One/One+ is a standard portable electrocardiograph that measures and records 12 channel electrocardiographic waveforms, measures ST segment level changes and gives real time heart rate measurements.

- Intended use is equivalent to the intended use of the predicate Cardioline AR 1200 and CorScreen electrocardiograph.

Summary of Device Testing

The Gem Heart One/One+ has been tested under the same standards to its predicate device the Cardioline AR1200 and CorScreen, in accordance with the EN 60601-1 and IEC 60601-2-25, as well as for EMC tests EN60601-1-2 standards. The device has completely passed the tests and has shown full compliance to the standards.

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Conclusions

The intended use, indication for use and principle of operation are similar to the predicate devices with some distinct features that have been previously cleared which do not raise any new types of safety and effectiveness questions. Furthermore it has been demonstrated that the Gem Heart One/One+ has shown to have passed the same safety and effectiveness standards to its predicate device, Cardioline AR1200 and the CorScreen.

Based on the performance and characteristics of the Gem Heart One/One+ described above, it is demonstrated that it is substantially equivalent to the predicate device Cardioline AR 1200 and CorScreen electrocardiographs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Gem-Med S. L.
c/o Mr. Casey Conry
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
Melville, NY 11747

Re: K092576
Trade/Device Name: Gem Heart One/One+
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: August 19, 2009
Received: August 21, 2009

Dear Mr. Conry:

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.

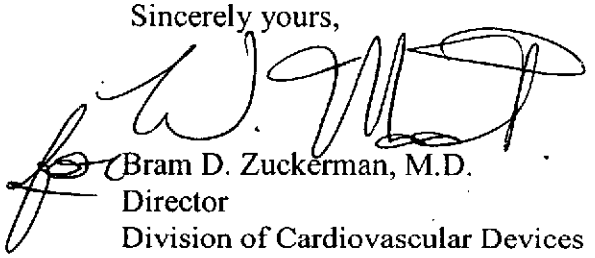
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

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Indication for Use

510(k) Number (if known):

Device Name: **Gem Heart One/One+**

Indications for Use:

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Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, ~~Office~~ of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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