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510(k) SUMMARY

Applicant: Michael Smith
President, General Devices
1000 River St.
Ridgefield, NJ 07657

Contact Person(s): Applicant and/or
Curtis Bashford
Vice-President, General Devices
1000 River St.
Ridgefield, NJ 07657

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Date Prepared: October 19, 2001

Device Information:

Trade/Proprietary Name:	EMS Telemedicine Option (for GEMS Series 4000)
Common Name:	ECG Demodulator/Display
Classification:	Class II
Panel:	Cardiovascular Devices Classification
Product Code:	Not Applicable

Predicate Device Information:

Trade/Proprietary Name:	GEMS Series 2000 (Modified DR-2C/PMC 100)
Common Name:	EMS Communications Console
Manufacturer	General Devices (same as applicant)
Classification:	Class II
510(k) No.	K896153
Trade/Proprietary Name:	Rosetta-Rx
Common Name:	Demodulator, Data Translator
Manufacturer	General Devices (same as applicant)
Classification:	Class II
510(k) No.	K002089

DESCRIPTION OF DEVICE

The EMS Telemedicine Option is an optional element of the GEMS Series 4000 communications console which provides the means for performing telemedicine functions, namely, communicating with and presenting information acquired from distant medical devices.

The GEMS Series 4000 communications console is a standard radio/telephony communications console used for voice and data communications. The GEMS Series 4000 communications console, without the EMS Telemetry Option is marketed for non-medical applications. Personal Computer (PC) based, it contains various means to interface to and control communications elements (i.e.; 2-way radio equipment, landline and wireless telephone) as which are commonly used for commercial and public safety (i.e.: police, fire and EMS) communications purposes.

With the EMS Telemedicine Option, the console can perform medical functions, such as communicating physiologic information (i.e.: single/12-Lead ECG and physiologic/non-physiologic data) with distant medical devices. The signal processing means employed for this includes: frequency modulation (FM), which is commonly used in EMS ECG telemetry applications; DTMF (touch-tone) signaling, which is commonly used for telecommunications signaling; Frequency Shift Keying (FSK), which is commonly used for data communications; as well as standard digital communications schemes such as modulation/demodulation (modem) communications. It also provides for the display and printing of physiologic information, such as single and 12-Lead ECG, and non-physiologic data, such as EMS Run ID, patient name, time of day, etc.

The EMS Telemedicine Option consists of hardware and software elements that are installed into the GEMS Series 4000 communications console. These hardware & software elements convert received information into a digital form compatible with standard PC functions, such as information presentation by a CRT monitor and hard-copy printouts. Signal processing is performed by a printed circuit board (PCB) that plugs into the console's PC Mother Board. The EMS Telemedicine Option's features and functions are similar to those found in this type of equipment, including the predicate devices (GEMS Series 2000 and Rosetta-Rx). The digital and analog technologies employed by the above stated purposes are commonly employed for this purpose and are well understood. The functioning of the heart rate meter and the performance of the demodulator/signal processing and display elements conform to ANSI/AAMI EC11-1991.

INTENDED USE

The intended use of the GEMS Series 4000 EMS Telemetry Option is to provide a means to communicate with distant medical devices in an EMS pre-hospital setting and to acquire and present information, such as single/12-lead ECG and physiologic/non-physiologic data which has been gathered by these devices.

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COMPARISON WITH PREDICATE DEVICES

Function or Specification	New Device	Predicate Devices	
	ECG Telemetry Option	GEMS Series 2000	ROSETTA-Rx
Form Factor	PC Option Card (for PC cabinet)	Desktop/rack mount cabinet	Option Card (for GEMS Series 2000) or Stand-Alone device
ECG Presentation Means	CRT Display (PC monitor), strip-chart recorder, laser printer	CRT Display (Vectored Beam CRT), strip-chart recorder, laser printer (w/Rosetta Option)	Stand-Alone: Laser printer Option Card: GEMS 2000 display and record features
Communication Means	Radio, landline telephone, wireless telephone	Radio, landline telephone, wireless telephone	Radio, landline telephone, wireless telephone
Digital Communication Interface	Serial (RS232), PC Modem	Serial (RS232)	Serial (RS232)
ECG & physiologic/non-physiologic data Formats	FM, DTMF, FSK, Modem	FM, DTMF	FM, DTMF, & FSK
Demodulation Means	Hardware/Software	Hardware	Hardware/Software
ECG Demodulation Format	1400 Hz Center frequency, 50 & 250 mV/Hz deviation	1400 Hz Center frequency, 50 mV/Hz deviation	1400 Hz Center frequency, 50 & 250 mV/Hz deviation
Data Demodulation Format	FSK 1.2kHz/1.6kHz	FSK 1.2kHz/1.6kHz(w/Rosetta Option)	FSK 1.2kHz/1.6kHz
User Controls	Pointing Device (mouse)	Mechanical front panel switches	Mechanical front panel switches
Power	+3.3, +/- 12 VDC from PC power supply	115Volt AC, 60Hz	Stand alone: External 9VDC adapter Option Card: +5, +/- 12 VDC from GEMS Series 2000 power supply

SUMMARY OF DIFFERENCES

The differences between the predicate and the new device relate primarily to: the form of system integration, in that the EMS Telemetry Option is an "add-on" to a non-medical device; the use of a modem to communicate information; the use of a pointing device, rather than mechanical control keys, an lastly, minor differences, such as form-factor, size, appearance and minor operating features.

SUMMARY OF NON-CLINICAL TESTS

The EMS Telemetry Option was subjected to non-clinical testing to insure proper performance. The testing consisted of the following parts:

- A determination of the ability of the EMS Telemetry Option to correctly and accurately communicate desired information from the acquisition device under simulated use conditions
- A determination to the ability of the EMS Telemetry Option to correctly convert the gathered information to the desired communications scheme under simulated use conditions
- A determination of the efficacy of the intended transmission schemes under simulated use conditions
- A determination of the ability of the EMS Telemetry Option to correctly and accurately acquire the information from the transmission means under simulated use conditions
- A determination of the ability of the EMS Telemetry Option to correctly convert the gathered information for presentation by the desired presentation means and accurately present this information under simulated use conditions

DISCUSSION OF HOW TEST RESULTS SUPPORT SUBSTANTIAL EQUIVALENCY

The testing that was performed on the EMS Telemetry Option demonstrates that the system is substantially equivalent to the predicate devices in that physiologic information acquired by an external source was reliably and accurately received and reconstructed for presentation at the far end.

CONCLUSION DRAW BY NON-CLINICAL TESTING

The conclusions draw by the non-clinical testing indicate that the EMS Telemetry Option/EMS Telemetry Option successfully perform the intended task under normal use conditions. The system behaved as expected and demonstrates the application of well-understood technology as well as the absence of any electrical risk factors to the patient.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Mr. Michael Smith
President
General Devices
1000 River St.
Ridgefield, NJ 07657

Re: K013533
Trade Name: EMS Telemedicine Option (for GEMS Series 4000)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: October 19, 2001
Received: October 23, 2001

Dear Mr. Smith:

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.

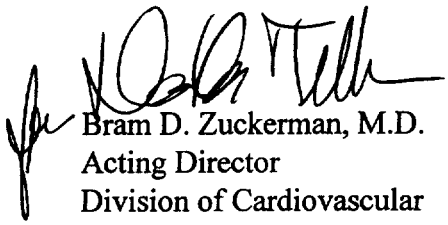
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

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INDICATIONS FOR USE STATEMENT

PMN 510(k) Number: K013533

Device Name: ECG Telemedicine Option (for GEMS Series 4000)

Indications For Use:

The ECG Telemedicine Option for the GEMS Series 4000 Communications Console is indicated for use when it is desired to communicate with distant medical devices in an EMS pre-hospital setting and to acquire and present information, such as single/12-lead ECG and physiologic/non-physiologic data, or other physiologic information which has been gathered by these devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013533