K040663

JUN 3 0 2004

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510(k) SUMMARY

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR Part 870.2910, Molex Incorporated is hereby submitting the 510(k) Summary for the EMS-Enable (formerly known as Orange Box) and EMS-Hub (formerly known as Orange Crate). Please note that Molex Incorporated has acquired Strategis Technologies LLC assets in regard to the Orange Box/Orange Crate and is applying for the 510(k) as a result of a 513(g) request made by Strategis Technologies LLC and responded to by Dr. Daniel G. Schultz (**reference** C040001).

Submitter:	Randall B. Jones Strategic Product Manager Molex Incorporated Integrated Products Division 2222 Wellington Ct Lisle, IL 60532	
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Telephone & Fax No:	Tel: +1 630.527.4334 Fax: +1 630.512.8630	
Date Prepared:	February 16, 2004	
Device Information:	*Trade/Proprietary Name:*	**TelEnable EMS System** comprised of EMS-Enable or Orange Box and EMS-Hub or Orange Crate
	Common Name:	Data and Fax Modulator/Demodulator and Receiving Station
	Classification:	Class II (See FDA Ref C040001)
Predicate Device Information:	*Trade/Proprietary Name:*	Rosetta-LT/Rosetta-Rx
	Common Name:	Modulator/Demodulator, Data Translator
	Manufacturer:	General Devices
	Classification:	Class II
	510(k) No:	K002089

1. 510(k) Summary of TelEnable EMS System

1.1. Description of TelEnable EMS System

The TelEnable EMS System provides a means of transmitting snapshots of physiologic waveforms and data over standard communications means such as the public switched telephone, analog cellular, or digital cellular networks. Such information is transmitted from a remote location using the EMS-Enable component to a receiving EMS Hub component located in a hospital.

The EMS-Enable component connects to portable ECG & standard monitor/defibrillator devices that can output their data via a standard fax modulator/demodulator (modem). The EMS-Enable decodes the touch tone dialing digits output by the monitor to determine which hospital to call. This analog information is converted into encrypted data packets that are suitable for transmission over digital and analog networks. The EMS-Enable is a self-contained, battery-powered device that is connected to a cell phone via a standard data cable compatible with the phone and a standard telephone adapter cable.

Standard fax output from the ECG monitor/defibrillator device is received by the EMS-Enable (as if was a standard telephone wall plug). The data is encrypted and converted into data packets to be transmitted over the digital cellular or other standard communication network. The EMS-Enable transmits the data packets over the communication network to the EMS Hub where the ECG fax can be printed out on a standard printer, saved in a data file, or printed out on a standard fax machine.

The EMS Hub component is located in the hospital and provides the interface between the remote EMS-Enable devices and the hospital. It is connected to the Public Switched Telephone Network (PSTN or standard telephone network) via standard telephone patch cables. It communicates with the EMS-Enable and depacketizes and decrypts the ECG fax into a format compatible with a printer, file, or standard fax machine.

The transmission formats supported by the EMS-Enable and EMS Hub include standard group 3 fax modulation formats, touch-tone signaling (DTMF), and standard interface protocols and schemes utilized by cell phones and cell phone carriers to transmit data.

1.2. Intended use

The TelEnable EMS System is intended to provide reliable transmission of ECG faxes acquired from a standard monitor/defibrillator. The EMS-Enable is designed to work remotely from the hospital and transmit ECG faxes (captured and formatted by the monitor/defibrillator). The transmission mechanism can be via any standard communication mechanism such as a landline, analog cell phone, digital cell phone, Bluetooth device, 802.11 device, or satellite phone.

The communication devices are off-the-shelf devices which have received the necessary FCC certifications and/or approvals to operate as radio devices. Examples of such devices include: cell phone handsets, Bluetooth modules with a serial interface, or standard serial modems.

In addition, the EMS Hub component of the system is capable of receiving standard faxes from any device, including ECG monitors, which may be transmitting such images over a standard PSTN (landline) circuit. Such images will not meet the quality of images transmitted using the EMS-Enable component, but will meet the quality of most laser fax machines.

The EMS-Enable component is not designed to interface directly to a PSTN through its RJ11 jack. This interface is the principle interface mechanism to portable ECG monitors/defibrillators.

1.3. Performance Comparison with Predicate Device(s)

Several devices, which are functionally similar, have previously been granted Class II, 510(k) approval from the FDA. While these predicate devices do not exactly match the functionally of the TelEnable EMS System, they are similar enough to be classified as legitimate predicate devices. These are listed in Table 1 and Table 2.

FUNCTION SPECIFICATION	(PREDICATE DEVICE) ROSETTA-LT	EMS-ENABLE
Function	Modulates ECG waveforms & data into FM & FSK transmission format.	Modulates ECG fax output into encrypted digital data packets
Communication Means	Radio, landline telephone, wireless telephone	Landline, analog and digital cell phone, digital wireless devices
Acquisition Device Connection	Hardwire (digital and analog)	Hardwire (digital and analog)
Transmission Device Connection	Hardwire and acoustic coupling for radio, landline, or wireless telephone	Hardwire for landline or data-enabled cell or wireless telephone
Modulation Means	Hardware/Software	Hardware/Software
ECG Modulation Format	1400 Hz Center frequency, 50 & 250 mV/Hz deviation	Standard fax output using any modulation format provided by the monitor.
Data & Signaling Format	DTMF, FSK & Serial	DTMF, V.92, Fax Group 3, Serial
Self-Calibrating	YES	Not necessary
Form Factor	Hand-held	Hand-held
Power Source	Internal 9V Battery, External 12V	Internal 12V Battery, External 12V

Table 1 EMS-Enable and Predicate Comparison

FUNCTION SPECIFICATION	(PREDICATE DEVICE) ROSETTA-RX	EMS HUB
Function	Demodulates FM ECG waveforms & FSK data.	Demodulates and decrypts digital packets into a file, printer, or standard fax output formats
Presentation Means	GEMS 2000 & laser printer	Standard Group 3 fax or standard laser printer
PC Interface	RS-232	RS-232, POTS, Ethernet, USB
Transmission Device Connection	Hardwire and acoustic coupling for radio, landline, or wireless telephone	Hardwire
Demodulation Means	Hardware/Software	Hardware/Software
ECG Modulation Format	1400 Hz Center frequency, 50 & 250 mV/Hz deviation	Standard fax output using any modulation format provided by the monitor.
Data & Signaling Format	DTMF, FSK & Serial	DTMF, V.92, Fax Group 3, Serial
Self-Calibrating	YES	Not necessary
Form Factor	Desktop cabinet	Desktop cabinet
Power Source	120 VAC, 50/60 Hz	90-220 VAC, 50/60Hz

Table 2 EMS Hub and Predicate Comparison

1.4. Summary of Differences

The primary difference between the predicate devices (system) and the TelEnable EMS System (TES) is that TES only transports ECG fax formatted snapshots from a remote location to a hospital. TES does not reformat the output (other than formatting automatically performed by fax machines to fit the image onto a page). TES provides data encryption (above that provided by the communications network) so that a casual interceptor of the data will not be able to read the information. Other differences relate to the packaging, circuits, software, battery type, appearance, brand name, manufacturer, and interface cables.

1.5. Summary of Non-clinical Trials

The TelEnable EMS System and its components were subjected to non-clinical testing to insure proper operation and performance. These tests included the following:

- Verification that the EMS-Enable could correctly and reliably received standard fax formatted information. These tests were performed under simulated use conditions and using standard fax machines as input devices.

- Verification that the EMS-Enable can correctly and reliably connect to and communicate with the standard communication devices. The specific devices tested were digital cell phone and land line connection.

- Verification that the EMS-Enable can correctly and reliably transmit the packetized and encrypted fax information. These tests were performed under simulated use conditions.

- Verification that the EMS-Enable can reliably received, encrypt, packetize, and send the received fax information in the format compatible with the EMS Hub. These tests were performed under simulated use conditions.

- Determined the efficacy of the EMS-Enable and EMS Hub under simulated wireless signal drop-out and signal-corruption conditions. These tests were performed under simulated use conditions.

- Verification that the EMS Hub can correctly receive the packetized and encrypted data. These tests were performed under simulated use conditions.

- Verification that the EMS Hub can correctly and reliably decrypt and output the fax data transmitted from the EMS-Enable. The outputs were to standard printer, file, and fax machines. These tests were performed under simulated use conditions.

1.6. How Test Results Support Substantial Equivalency

The testing that was performed on the TelEnable EMS System demonstrates that the system is substantially equivalent to the predicate devices in that the physiologic information (snapshots are encoded by an external monitor and output as a standard fax) was reliably and correctly transmitted and faithfully reproduced on the output device.

1.7. Conclusion Drawn by Non-Clinical Testing

The conclusions drawn by the non-clinical testing indicate that the TelEnable EMS System can successfully perform the intended tasks under normal use conditions; that the system behaved as expected; that the application of standard communication technologies in this environment can achieve predictable results; and the absence of 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

JUN 3 0 2004

Molex Incorporated
c/o Mr. Randall B. Jones
Strategic Product Manager
Integrated Products Division
2222 Wellington Ct
Lisle, IL 60532

Re: K040663
Trade Name: TelEnable EMS System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 1, 2004
Received: June 7, 2004

Dear Mr. Jones:

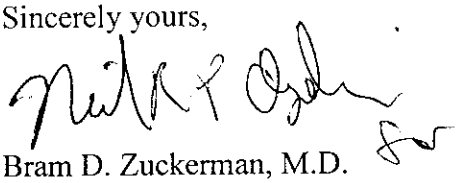
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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 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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): *K040663*

Device Name: *TelEnable EMS System*

Indications For Use:

The TelEnable EMS System provides a mechanism to transmit 12-lead ECGs from a portable ECG monitor to a central location such as a hospital. This system connects to the ECG via a standard POTS (Plain Old Telephone System) interface and communicates to the ECG via standard Group 3 facsimile (fax) protocol.

All information received by the TelEnable EMS System's mobile component (EMS-Enable) is relayed wirelessly to a central receiving station (EMS Hub). Such a station can be co-located in a hospital or at an EMS dispatch center.

The ECGs received may either be printed locally or forwarded, via fax, to the destination specified by the ECG operator.

No component of the TelEnable EMS System is connected directly to a patient. The TelEnable EMS System is non-invasive. The ECG monitor operator shall observe all the same precautions when connecting the ECG monitor to the EMS-Enable component as when connecting the ECG monitor directly to the PSTN (Public Switch Telephone Network).

Prescription Use_____ AND/OR Over-the-Counter Use____X_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040663