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Date: 2002

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92(c)**
Envoy Patient Monitor - Device Modification:
Special 510k for new ECG/Telemetry module

Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
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Tel: +972-8-9323333 Fax: +972-8-9328510	
Contact person:	Asher Kassel, Director of Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Asher Kassel, Director of Regulatory Affairs

Product Name:
Proprietary: ENVOY
Common: Physiological Patient Monitor
Mennen Medical Part Number: 550-010-000 (full system)
554-000-010 (CPU only)

12L ECG/Telemetry module (receiver): P/N: 551-119-000
12L ECG/Telemetry module (transmitter): P/N: 551-119-100

FDA Classification of Envoy Patient Monitor:

Classification Name:	Arrhythmia Detector and Alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	74 DSI

FDA Classification of ECG/Telemetry Module:

Classification Name:	Arrhythmia detector and alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	DSI

Performance Standards:

None promulgated

Voluntary Standards:

- IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1-2: General Requirements for Safety. Collateral Standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-2-27: Safety of Electrocardiographic monitoring
- AAMI/ANSI ES1: Safe Current Limits for Electromedical Apparatus, and
- AAMI/ANSI EC13: Cardiac Monitors, Heart Rate Meters and Alarms.

Predicate Device:

MENNEN MEDICAL ENVOY PATIENT MONITOR (K011784).

Device Description - Envoy Patient Monitor:

The Envoy is a multiparameter physiological patient monitor, capable of monitoring:

- ECG/Heart Rate
- invasive blood pressure
- non-invasive blood pressure
- respiration
- pulse oximetry
- two temperature channels
- cardiac output
- $eTCO_2$

The Envoy bedside patient monitor consists of a main processing unit, a mountable color monitor, and a module rack housing the various Mennen Medical plug-in *vital signs* modules. The modules monitor the patient's vital signs. Up to six internal modules can be plugged into a module rack. The Envoy can accommodate two module racks. The vital sign data derived from the modules by the Envoy are presented on the monitor as waveform and numeric displays. The Envoy vital signs modules acquire vital signs data from the patient, and display their waveforms and alarms indications on the Envoy display unit. Vital signs and waveform information are displayed simultaneously on the Envoy Display Unit. Up to 8 traces can be displayed at any one time.

The Envoy is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such it is not a life supporting, nor life sustaining device; nor is it implantable and therefore sterility is not a consideration.

The Envoy is not a kit, does not contain any drug or biological products and is not for prescription use. The sale of and use of the Envoy is restricted to qualified medical personnel only.

Functional Description and intended use of of the ECG/Telemetry module:

The 12L ECG telemetry module can be used instead of the regular ECG module to monitor the ECG of patients whose condition enables them to be mobile.

ECG is monitored by attaching electrodes to the patient's chest and by connecting the electrodes via a cable to the ECG module in the patient monitor. A 10-wire cable enables ECG monitoring via 12 ECG leads, while a 5-wire cable enables the display of 7 ECG leads.
The ECG signal is used to detect the QRS complex, and for the detection and alarm of Heart Rate, Arrhythmia and ST changes.

The ECG telemetry does away with the need to connect the patient cable to the bedside monitor; instead, the patient cable is connected to a lightweight transmitter (240 gram) carried by the patient. This enables the patient to move around freely while being monitored by the Envoy patient monitor.

The telemetry operating range is 15 meters (with no barrier) from the receiver.
For a longer operating distance, you need to add an optional Antenna network.

The Telemetry system can use up to 256 channels working in parallel. Each telemetry transmitter is coupled to one telemetry receiver. The telemetry receiver is located in a ECG Telemetry module connected to the Envoy module rack.

The single width ECG Telemetry module is intended to be used to monitor 12 lead ECG for patients monitored by the bedside Envoy monitor. Telemetry monitoring is used when the condition of the patient enables him/her to move around.

This application is typical to Cardiology Step Down units and to post Open Heart Surgery units, where the patient is connected to a multi parameter monitor at the first stage of hospitalization, and as his condition improves, he is encouraged to be ambulatory with only ECG monitoring by telemetry

ENVOY Intended Use:

The Envoy is intended for use as a multiparameter physiological patient monitoring system.

The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the Envoy to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical Envoy is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Summary of the technological characteristics of the new ECG/Telemetry module (OEM Mortara technology):

The following tables summarize data on the Mennen Medical Envoy **12L ECG/Telemetry** module (modified device):

Envoy 12 L ECG/Telemetry module	
Part Number:	551-119-000 (module with receiver) 551-119-100 (transmitter)
Monitored Parameters:	• ECG • Heart Rte
Module size:	**Single slot** Height: 10.0cm (4.0 in) Width: 4.0 cm (1.6 in) Depth: 14.0 cm (5.5 in)

Features	**Envoy 12L ECG/Telemetry module**
Monitored Leads	Single block 10 lead (12L)
Sampling Rate and Resolution	500 Hz sampling rate 20 bit resolution
Frequency Response – analog output	Diagnostic: 0.05 to 150 Hz Monitor: 0.5 to 40 Hz Exercise: 1.0 to 25 Hz
Input Impedance	47 megohoms
Baseline Recovery	within 3 sec, 1 sec after lead switch
Input Dynamic Range	700 mv.
Electrode offset tolerance	Electrode offset tolerance
Pacemaker Detection and Rejection	10,000 s/sec/channel used for pacemaker artifact detection
Patient Isolation	Transmitter is battery operated (internally powered) and fully isolated
Heart Rate (HR) Counting	20 to 300 BPM
HR Accuracy	± 2 BPM. Values below 20 are recorded as zero
QRS Detection Range	0.25 to 5.0 millivolt height 70 to 120 milliseconds width

Features	**Envoy 12L ECG/Telemetry module**
Leads analyzed for	Heart Rate and Arrhythmia Configuration; Top two displayed
HR Alarm Settings	20 (Low) to 350 (High), non-overlapping
Lead Fault Sense	When ECG electrode is interrupted or becomes marginal
Defib. Pulse Protection	Defibrillator protected when used with OEM patient cable
Degree of protection against electrical shock	Transmitter is Type CF

Alarm Indications:	**Envoy 12L ECG/Telemetry module**
ECG	Visual & Sound
Heart Rate	Visual & Sound
Display Functions	**Envoy 12L ECG/Telemetry module**
Change ECG Lead Selection	Yes
Display of Arrhythmia Information	Yes
Data Review: Trends	Yes
Data Review: Tabular	Yes
User defined Configuration Setup	Yes
User defined Default Settings	Yes

Conclusion of comparison of technological characteristics:

We consider the Envoy ECG/Telemetry module to be substantially equivalent to the Envoy 12 Lead ECG/Resp. module and we submit that any differences between the two modules:

- fall within the scope of a Special 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

Testing

The Envoy 12L ECG/Telemetry module has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies to applicable industry and safety standards.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2002

Mennen Medical Ltd.
c/o Mr. Asher Kassel
Regulatory Affairs
P.O. Box 102
Rehovot 76100
ISRAEL

Re: K023798
Trade Name: The Envoy
Regulation Name: Arrhythmia Detector & Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: DSI
Dated: November 12, 2002
Received: November 14, 2002

Dear Mr. Kassel:

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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

The Envoy is intended for use as a multiparameter monitoring system.

The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the Envoy *to* monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical Envoy is intended for sale as a system for remote monitoring and recording patient information or any in-hospital application requiring remote patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Division of Cardiovascular & Respiratory Devices
510(k) Number K023798

Prescription Use X
(Per 21 CFR 801.109)