Mennen Medical Ltd.,
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Date revised 24nd July, 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 SpO2 module (Masimo)

Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
Address:	4 Hayarden Street, Yavne, 81228, Israel
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(See Note on page 11 re the new address of Mennen Medical Ltd.)

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)

New SpO2 module (Masimo) P/N: 551-139-000

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 SpO2 Module:

Classification Name:	Oximeter
Classification Number:	21 CFR 870.2700
Classification:	Class II
Product Code:	74 DQA

Performance Standards:

None promulgated

Voluntary Standards:

UL 2601-1, IEC 60601-1 for electrical safety for medical equipment
AAMI/ EC 11 - Diagnostic electrocardiograph devices (1991)
AAMI/ EC 13 - Cardiac monitors, heart-rate meters, alarms (1992)
AAMI/ ES 1 - Safe current limits for electromedical apparatus (1993)
IEC 60601-1:
General Requirement for Safety for Medical Electrical Systems - part 1, (1988); Amendment 1 – 1991-11
Amendment 2 – 1995-03
IEC 60602-2-27:
Medical electrical equipment, Part 2, (1994)
Requirements for safety of electrocardiograph monitoring equipment.
ISO 9919:
Pulse oximeters for medical use requirements (1991)

Predicate Device:

MENNEN MEDICAL ENVOY PATIENT MONITOR (K001120).

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.

Functional Description of the new SpO2 module (OEM Masimo technology):

The SpO2 module is the source of all pulse oximetry data in the ***Envoy*** bedside monitor.

SpO2 is measured to determine a monitored patient's arterial oxygen saturation and pulse rate. Arterial oxygen saturation is the percentage of oxygenated hemoglobin in relation to the total hemoglobin. For example, if 95 percent of the hemoglobin molecules in the arterial red blood cells combine with oxygen, the blood has an oxygen saturation of 95 percent. The Sp02 numeric value represents the percentage of hemoglobin molecules that have combined with oxygen molecules to form oxyhemoglobin.

The SpO2 module is housed in the *Envoy* module rack, where it occupies a single slot.

The *Envoy* bedside monitor measures oxygen saturation using the Pulse Oximetry method. This continuous, non-invasive method measures the light absorption in the patient's tissue (for example, a finger of the hand or foot) to a receiver on the other side.

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 SpO2 module (OEM Masimo technology):

The following tables summarize data on the Mennen Medical Envoy Envoy SpO2 Masimo module (modified device):

Envoy SpO2 Masimo module	
Part Number:	551-139-000
Monitored Parameters:	• SpO2 Oxygen saturation • Pulse waveform • Pulse rate volume
Module size:	**Single slot** Height: 10.0cm (4.0 in) Width: 4.0 cm (1.6 in) Depth: 14.0 cm (5.5 in)

Envoy SpO2 Masimo module	
Saturation range:	1% to 100% Sp02
SpO2 Accuracy:	Adults: 70 % - 100 % ± 2 digits Neonates: 70 % - 100 % ± 3 digits
Pulse Rate range:	25 to 240 BPM ±3 BPM
Low saturation alarm limits:	50% to 100%
Data Stotrage (in mainframe):	O2 saturation and Pulse Rate Alarm event markers Photoplethysmography waveform

Envoy SpO2 Masimo module	
Features:	Red & Infrared light Tissues absorption method
	Waveform display
	Pulse rate derived from SpO2 with independent alarm limits
	Pulse sound distinct in tone and pitch from QRS tone
	Variation in the pulse sound pitch with SpO2 value
	Signal strength display
Technical Alarms:	"Cable out" and "Relocate probe"

The major difference between the Envoy SpO2 **Nellcor** module and the Envoy SpO2 **Masimo** module is the addition of Masimo proprietary **SET** technology. **SET** signal processing is a Masimo developed technology that provides accurate monitoring during:

- Patient Motion or Movement
- Low Perfusion (low signal amplitude)
- Intense Ambient Light (lighting or sunlight)
- Electro surgical Instrument Interference

Conclusion of comparison of technological characteristics:

We consider the Envoy Sp2 Masimo module to be substantially equivalent to the Envoy SpO2 Nellcor module and we submit that any differences between the two modules:

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

Testing

The Envoy SpO2 Masimo 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.

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

Signature:

Asher Kassel

Asher Kassel
Director of Regulatory Affairs
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. Asher Kassel
Director of Regulatory Affairs
Mennen Medical Limited
4 Hayarden Street, Yavne
P.O. Box 102
Rehovot 76100
ISRAEL

Re: K022168
Trade/Device Name: ENVOY Patient Monitor
Regulation Number: 21 CFR 870.2700, 870.1025
Regulation Name: Oximeter, Arrhythmia detector and alarm
Regulatory Class: III
Product Code: DQA, DSI
Dated: July 2, 2002
Received: July 3, 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.

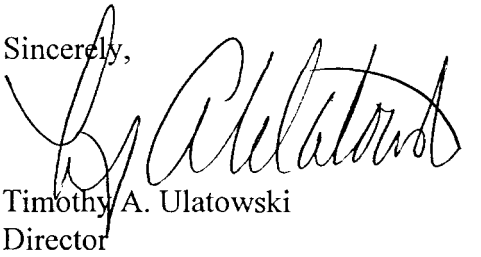
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022168

✓ PRESCRIPTION USE