

MENNEN

MEDICAL LTD.

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K974510

APR 14 1998

Date: 30 October 1997
To: Food and Drug Administration
Center for Devices and Radiological Health Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville MD 20850
Attn.: Document Control Clerk
From: Kenneth Raichman
Director of Regulatory Affairs
Topic: **510(k) Summary**
ENVOY Patient Monitor
Safety and Effectiveness

Product Name

Proprietary: ENVOY
Common: Physiological Patient Monitor

Establishment Registration Number and Address

Registration Number 9611022
Mennen Medical LTD.
Ken Raichman, Director of Regulatory Affairs
Kiryat Weizmann Science Park
Rehovot 76100 Israel
Tel: 972-8-938-3030

Classification (Section 513)

Classification: Class III
Panel: Anesthesiology and Respiratory/Cardiology

Performance Standards

None promulgated

Voluntary Standards

AAMI/ANSI ES1 Safe Current Limits for Electromedical Devices
AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms
AAMI/ANSI SP-10, Electronic or Automated Sphygmomanometers
IEC 601-1 Medical Electrical Equipment
IEC 601-2-27 Safety of electrocardiographic monitoring
IEC601-2-30 Requirements for automatic cycling indirect blood pressure monitoring
IEC601-2-34 Requirements for Invasive Blood Pressure monitoring equipment

Predicate Devices

MENNEN MEDICAL HORIZON XL (K911616).
HEWLETT-PACKARD M1175/26A COMPONENT MONITORING SYSTEME (K941811).

Date Prepared: 30 October 1997

Device Description

ENVOY is hospital based, multiparameter patient monitor for monitoring physiological patient vital signs.

The **ENVOY patient monitor** system consists of the following components:

- Main Processing Unit
- Display Unit
- Module Rack
- Vital Signs Plug-in Modules

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 vital signs modules interface with readily available physiologic transducers through electrically isolated patient input connections. After amplification, the signals are digitized, analyzed and displayed. All processing and alarm determination for ECG, Respiration and Invasive Blood Pressure is made using proprietary algorithms and software based on previously marketed Mennen Medical monitoring devices tested against well known and accepted data bases that present representative examples of waveform artifact to be encountered in real case conditions. SpO2 and Non-Invasive Blood Pressure Modules use software/hardware from vendors whose products already appearing on the USA market.

Information from each vital sign is presented in a separate portion of the display. Each vital sign is labeled for identification and numeric value. Displayed Vital sign information can include: Primary Vital Sign Name, Waveform, Vital Sign Numeric Value, Alarm Status Message.

Operation of the ENVOY is accomplished by interaction with front panel controls on the main processor unit. A quick-knob control allows direct interaction with displayed menus for direct parameter selection and setup. Where manual entry of alphanumeric information is required, a menu keyboard menu is display.

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, or life sustaining device; nor is it implantable and therefore sterility is not a consideration.

ENVOY complies with IEC 601-1 Medical Electrical Equipment, IEC 601-2-27 Safety of electrocardiographic monitoring, IEC 601-2-30 Requirements for automatic cycling indirect blood pressure monitoring, AAMI/ANSI SP-10 Electronic or Automated Sphygmomanometers, IEC 601-2-34 Requirements for invasive blood pressure monitoring, AAMI/ANSI ES1 Safe Current Limits for Electromedical Apparatus, and AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms. ENVOY is not a kit, does not contain any drug or biological products and is not for prescription use.

Indications for Use:

The ENVOY Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, and Pulse Oximetry. The ENVOY may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Substantial Equivalency Information:

The following tables summarize data on the Mennen Medical ENVOY, the Mennen Medical Medical HORIZON XL (K911616), and the Hewlett-Packard M1175/26A Component Monitoring System (K941811), both are substantially equivalent devices, available in the U.S. market.

Displayed Parameters	Mennen Medical ENVOY Patient Monitor	Mennen Medical HORIZON XL Patient Monitor	H-P M1175/26A Component Monitoring System
ECG	Yes	Yes	Yes
Heart Rate	Yes	Yes	Yes
Invasive BP	Yes	Yes	Yes
Noninvasive BP	Yes	Yes	Yes
Pulse Oximetry	Yes	Yes	Yes
Respiration	Yes	Yes	Yes
Temperature	Yes	Yes	Yes

Alarm Indications:	Mennen Medical ENVOY Patient Monitor	Mennen Medical HORIZON XL Patient Monitor	H-P M1175/26A Component Monitoring System
ECG	Visual & Sound	Visual & Sound	Visual & Sound
Heart Rate	Visual & Sound	Visual & Sound	Visual & Sound
Invasive BP	Visual & Sound	Visual & Sound	Visual & Sound
Noninvasive BP	Visual & Sound	Visual & Sound	Visual & Sound
Pulse Oximetry	Visual & Sound	Visual & Sound	Visual & Sound
Respiration	Visual & Sound	Visual & Sound	Visual & Sound
Temperature	Visual & Sound	Visual & Sound	Visual & Sound
Graded according to Severity: audio, visual	YES	YES	YES
Technical Alarms (INOPS)	YES	YES	YES
Resetting/Suspending Alarms - silence tone, automatic reactivate after set interval	YES	YES?	YES

Measurement Principle	Mennen Medical ENVOY Patient Monitor	Mennen Medical HORIZON XL Patient Monitor	H-P M1175/26A Component Monitoring System
Heart Rate	From ECG, Pulse Oxymetry, Blood Pressure	From ECG	From ECG
Invasive BP	Pressure Transducer	Pressure Transducer	Pressure Transducer
Noninvasive BP	Arm Cuff	Arm Cuff	Arm Cuff
Pulse Oximetry	Infra-red Sensor	Infra-red Sensor	Infra-red Sensor
Respiration	From ECG	From ECG	From ECG
Temperature	Temp probe	Temp probe	Temp probe

Auxiliary Functions	Mennen Medical ENVOY Patient Monitor	Mennen Medical HORIZON XL Patient Monitor	H-P M1175/26A Component Monitoring System
Change ECG Lead Selection	YES	YES	YES
Display of Arrhythmia Information	YES	YES	YES
Change BP Range/Scale	YES	YES	YES
Data Review: Trends	YES	YES	YES
Data Review: Tabular	YES	YES	YES
User defined Configuration Setup	YES		YES
User defined Default Settings	YES		YES

Alternative Practices and Procedures:

The information displayed by ENVOY is acquired by similar techniques used by other commercially available equipment within the same product category. Like the referenced predicate products, ENVOY provides vital signs information for a patient. This enables a single operator to monitor several parameters for significant clinical events. Whenever an alarm is detected the parameter and alarm type are identified. Viewing the patient's current physiological waveforms on ENVOY allows the user to qualify the severity of the alarm condition.

ENVOY integrates the measured vital signs information for a patients into a single display, and provides a uniform method for interaction and comparison.

Marketing History

ENVOY has no marketing history.

Summary of Validation

ENVOY is a physiologic patient monitor. Device validation studies were performed to verify that conditions detected by the "bedside device" were completely and accurately reported and displayed on the ENVOY.

Validation:

ENVOY was tested against Mennen Medical's Design Specifications, in accordance with the procedures identified in Part 7 Section 2, with results as presented in Part 7 Section 3.

Simulated inputs were used to test the vital signs monitored by the ENVOY. The objective of this study was to compare the performance of the ENVOY against voluntary industrial standards where appropriate, and Mennen Medical design standards where appropriate, or where industrial standards did not exist.

Software validation was tested against Mennen Medical's test plan protocol. Simulated patient waveforms were generated using a DNI Nevada Inc. 217A Patient simulator and Mennen Medical simulators.

ECG/Heart Rate response was evaluated against the AAMI/ANSI Cardiac Monitors, Heart Rate Meters, and Alarms Standards.

Testing of other Vital signs was performed against Mennen Medical's Design specifications. Measurements were within published specifications.

Patient safety was confirmed by testing EN60601-1 and AAMI/ANSI Safe Current Limits for Electromedical Apparatus standard.

ENVOY complies with IEC 601-1 requirements for flammability, mechanical abuse, temperature and humidity. Environmental testing was conducted pursuant to IEC-68-2-1 (Cold), IEC-68-2-2 (Dry Heat), IEC-68-2-3 and IEC-68-2-56 (Damp heat steady state), IEC-68-2-13 (Low air pressure), IEC-68-2-6 (Vibration - sinusoidal), IEC-68-2-36 (Random vibration wide band), IEC 68-2-27 (Shock) and MIL-STD-810E.

EMC testing, pursuant to IEC 601-1-2, IEC 801-1/2/3/4 and 5, EN 55011 and CISPR 16 was conducted and compliance verified.

Non-invasive blood pressure was evaluated for IEC601-2-30 Requirements for automatic cycling indirect blood pressure monitoring. The performance of the ENVOY was compared against another automated non-invasive blood pressure device (Mennen Medical HORIZON XL). The study followed the AAMI Electronic or Automate Sphygmomanometers Standard SP-10 (Refer to Part 8 for NIBP clinical trials and results).

Clinical validation studies of the Pulse Oximetry Module are present in Part 8 of the submittal.

Conclusions Drawn from Validation Studies:

The results of the validation studies indicate that ENVOY is safe, effective and poses no new risks when compared against the Mennen Medical Design Standards, and equipment already in clinical use.

Software Validation

Software validation verified the functionality of the Mennen Medical ENVOY from a "black box" approach. Validation was performed by a persons other than those involved in the design of the system. This independent audit confirmed that the system (both hardware and software) met the specified requirements.

Software Validation Plan:

The software validation plan tested the following areas:

Verified that the system performed according to specified requirements.

Verified the system by exercising user input and assuring correct output.

Checked for hidden functionality.

Verified that the system recovers from errors.

The SOFTWARE VALIDATION PLAN was reviewed and approved by Mennen Medical's Engineering and Quality Assurance Departments, insuring that the tests were both valid and thorough.

The SOFTWARE VALIDATION PLAN was executed and the results were analyzed by the Quality Assurance and Engineering Departments. The results met expectations and the software was approved for release, pending clearance of the 510(k) process.

MENNEN MEDICAL LTD.



Kenneth Raichman,
Director of Regulatory Affairs

Enclosures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Mr. Kenneth Raichman
Director of Regulatory Affairs
MENNEN MEDICAL Ltd.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100 Israel

Re: K974510
Envoy Patient Monitor
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: March 5, 1998
Received: March 12, 1998

Dear Mr. Raichman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

K974510

Device Name

ENVOY PATIENT MONITOR

Indications for Use:

The ENVOY Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, and Pulse Oximetry. The ENVOY may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

MRI Compatibility Statement:

The ENVOY is not compatible for use in a MRI magnetic field.

(DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jackie Telli

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974510

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use
(Optional Form 1-2-96)