OCT 8 1999

K983864

MENNEN

MEDICAL LTD.

MENNEN MEDICAL LTD.
Kiryat Weizmann Science Park
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Date: 30 August 1999

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

Attn.: Document Control Clerk

From: Kenneth Raichman
Director of Regulatory Affairs

Topic: **510(k) Summary**
ENVOY Patient Monitor - EtCO2 module
Safety and Effectiveness

Product Name

Proprietary: ENVOY EtCO2 Module
Common: End-Tidal 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
Product Code DSI III
Panel: Anesthesiology and Respiratory/Cardiology

Performance Standards

None promulgated

Voluntary Standards

IEC 601-1, IEC 601-1-1, IEC 601-1-2, IEC 601-1-4, EN1441, AAMI/ANSI Standards

Predicate Devices

MENNEN MEDICAL MERCURY (K940081)
PRYON SC300 (CAP 400 AT - K935272)

Date Prepared: 30 October 1998

Date Revised: 29 August 1999

Device Description

ENVOY EtCO2 is a hospital based module, for monitoring EtCO2 physiological patient vital signs.

ENVOY vital signs EtCO2 module acquires vital signs data from the patient, and displays the patients waveform and alarms indication on the ENVOY display unit. This information is displayed simultaneously on the ENVOY Display Unit.

All processing and alarm determination for EtCO2 is made using Pryon technology based on currently marketed Pryon monitoring devices.

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.

Selection of the EtCO2 functions 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.

Indications for Use:

Mennen Medical is extending the current Indications for Use statement for the Envoy to include EtCO2 monitoring.

Substantial Equivalency Information:

Mennen Medical submits that the ENVOY EtCO2 is substantially equivalent to the EtCO2 of the MENNEN MEDICAL MERCURY (K940081) and the Pryon CAP 400 AT - K935272.
The following tables summarize data on the Mennen Medical ENVOY employing the Pryon Duet board, and the Mennen Medical MERCURY.

Displayed Parameter Message	Alarm Indication	Mennen Medical ENVOY Patient Monitor	Mennen Medical MERCURY Patient Monitor
etCO2	Yes	Yes	Yes
Respiration Rate	Yes	Yes	Yes
inCO2	Yes	Yes	Yes
Apnea Information	Yes	Yes	Yes
EtCO2 Alarm Limits	Yes	Yes	Yes
Display Units	Yes	Yes	Yes
Display Labels	Yes	Yes	Yes
Sweep Speed	N/A	Yes	Yes
Grid	N/A	Yes	Yes

Marketing History

EtCO2 has a well known marketing history.

Summary of Validation

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 EtCO2 was tested against Mennen Medical's Design Specifications, in accordance with the procedures identified in Part 3, with results as presented in Part 5.

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 as presented in Part 5. Simulated conditions were evaluated against defined gas concentrations of CO2.

Conclusions Drawn from Validation Studies:

The results of the validation studies indicate that ENVOY EtCO2 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 EtCO2 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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1999

Mr. Asher Kassel
Mennen Medical Ltd.
Kiryat Weizmann Science Park
P.O. Box 102, Rehovot 76100
ISRAEL

Re: K983864
ETCO2 Module of Envoy Patient Monitor
Regulatory Class: II (two)
Product Code: 73 CCK and 74 MHX
Dated: August 16, 1999
Received: August 18, 1999

Dear Mr. Kassel:

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 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). 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 (Premarket 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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)

K983864

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, Pulse Oximetry and EtCO2. 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 MRI magnetic field.

(DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Form 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983864