

AUG 12 1998

K982697

**510(k) Summary****Product Name**

Proprietary: ENSEMBLE  
 Common: Physiological Monitoring System, Central Station Display Terminal

**Establishment Registration Number and Address**

Registration Number 9611022  
 Mennen Medical LTD.  
 Alan Schwebel, Ph.D.  
 President  
 Kiryat Weizmann Science Park  
 Rehovot 76100 Israel  
 Tel: 972-8-938-3030

**Classification (Section 513)**

Classification: Class III  
 Classification Number 74 DSI  
 Panel: Anesthesiology and Respiratory/Cardiology

**Substantial Equivalency Information:**

The following tables summarize data on the Mennen Medical ENVOY (K974510) and the Mennen Medical Medical HORIZON XL (K911616 ) Patient monitors. The Ensemble Central Station is able to display the signals that are transmitted to it by the patient monitor to which it is connected via the communication network.

Displayed Parameters	Mennen Medical ENVOY Patient Monitor	Mennen Medical HORIZON XL Patient Monitor	Equivalency Statement
ECG	8 waveforms display	3 waveforms display	Ensemble does not analyze waveforms; it only <i>displays</i> them.
Heart Rate	numerical	numerical	No difference
Invasive BP	waveform/numerical	waveform/numerical	No difference
Noninvasive BP	numerical	numerical	No difference
Pulse Oximetry	waveform/numerical	waveform/numerical	No difference
Respiration	numerical	numerical	No difference
Temperature	numerical	numerical	No difference

<b>Alarm Indications:</b>	<b>Mennen Medical ENVOY Patient Monitor</b>	<b>Mennen Medical HORIZON XL Patient Monitor</b>	<b>Equivalency Statement</b>
Arrhythmia	Yes	Yes	No difference
Heart Rate	Yes	Yes	No difference
Invasive BP	Yes	Yes	No difference
Noninvasive BP	Yes	Yes	No difference
Pulse Oximetry	Yes	Yes	No difference
Respiration	Yes	Yes	No difference
Temperature	Yes	Yes	No difference
Graded according to Severity: audio, visual	Yes	Yes	No difference
Technical Alarms (INOPS)	Yes	Yes	No difference
Resetting/Suspending Alarms - silence tone, automatic reactivate after set interval	Yes	Yes	No difference
<b>Auxiliary Functions</b>	<b>Mennen Medical ENVOY Patient Monitor</b>	<b>Mennen Medical HORIZON XL Patient Monitor</b>	<b>Equivalency Statement</b>
Change ECG Lead Selection	Yes	Yes	No difference
Display of Arrhythmia Information	Yes	Yes	No difference
Change BP Range/Scale	Yes	Yes	No difference
Data Review: Trends	Yes	Yes	No difference
Data Review: Tabular	Yes	Yes	No difference

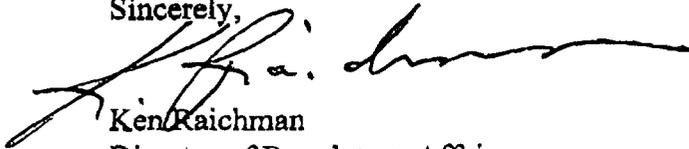
**Substantial Equivalency**

Mennen Medical deems the operation of the Ensemble opposite the Mennen Medical Envoy patient monitor to be substantially equivalent to the operation of the Ensemble opposite the Mennen Medical Horizon XL patient monitor.

Mennen Medical considers all information in this submittal to be confidential.

Please contact the undersigned either by  
telephone: 972-8-938-3030, Fax: 972-8-940-6519 or  
E-mail: kenr@mmi.co.il

Sincerely,



Ken Raichman  
Director of Regulatory Affairs  
MENNEN MEDICAL LTD.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 12 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kenneth Raichman  
Mennen Medical Ltd.  
Kiryat Weizmann Science Park  
P.O.B. 102  
Rehovot 76100  
ISRAEL

Re: K982697  
Ensemble Central Station Monitor with Envoy Patient Monitor  
Regulatory Class: III (three)  
Product Code: 74 DSI  
Dated: July 30, 1998  
Received: August 3, 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 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.

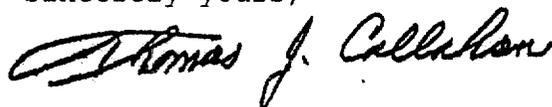
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Kenneth Raichman

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

Enclosure



**MENNEN MEDICAL LTD.**  
Kiryat Weizmann Science Park  
P.O.B. 102  
Rehovot 76100 Israel  
Tel: 972-8-9383030  
Fax: 972-8-9406519

Partners In Patient Care

**Special 510(k): K982697 - Modification to the Ensemble Central Station**

Ensemble Central Station monitor with Envoy Patient monitor

**Indications for Use:**

ENSEMBLE includes the essential features of a central station monitor for up to 12 patients. It can display vital signs information collected from bedside patient monitoring devices such as: ECG/Heart Rate, Arrhythmia (basic and extended alarms), ST Segment, Respiration, Temperature, Invasive Blood Pressure, Noninvasive Blood Pressure, Pulse Oximetry, and End Tidal carbon-dioxide. The ENSEMBLE may be used in system application in many different clinical specialties within the hospital.

  
(Signature)

Kenneth Raichman  
Director of Regulatory Affairs  
Mennen Medical Ltd.

Date: August 10, 1998

*Mark Kramer*

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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_

*PRESCRIPTION USE*