K970358

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mennenmedical MENNEN MEDICAL LTD.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100 Israel
Tel: 972-8-938-3030
Fax: 972-8-940-6519

Date: 10 November 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**
ENSEMBLE Central Station Monitor
Safety and Effectiveness

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
Panel: Anesthesiology and Respiratory/Cardiology

Performance Standards

None Established.

Voluntary Standards

AAMI/ANSI ES11 Safe Current Limits for Electromedical Devices
AAMI/ANSI EC13, Cardiac Monitors, Heart Rate Meters and Alarms
UL-544

Predicate Devices

MENNEN MEDICAL COMPREHENSIVE CENTRAL STATION (K892066).
HEWLETT-PACKARD M2360A WAVEVUE CENTRAL MONITOR (K921014).

Date Prepared

10 November 1997

Device Description

ENSEMBLE is hospital based, multi-patient, multi-parameter display terminal. As such, it is a component in a physiological patient vital signs monitoring system.

A system consists of any of the several possible combinations of the following components:

Bedside Devices
HORIZON XL patient monitor, and/or
219 TELEMETRY RECEIVER/TRANSMITTER with NS-7,
(K911616, and K895395, respectively)
Ethernet™ Communication Network
Documentation Peripherals (Chart Recorders and Laser Printers), and
ENSEMBLE Central Station Monitor.

ENSEMBLE acquires patient vital signs, waveforms and alarm indications from Mennen Medical HORIZON XL and 219 TELEMETRY systems. All processing and alarm determination is made in these "bedside devices", using proprietary algorithms and software contained therein. Processed information is communicated from the bedside devices to one or more ENSEMBLE Central Station Monitors by the Mennen Medical ENSEMBLE system Ethernet™ network. If documentation is requested, information is transmitted to the appropriate Documentation Peripheral, using the same network.

Although ENSEMBLE does not make alarm determinations, it does provide users with a remote interaction capability, allowing users to make changes to both parameter and alarm settings in the remote bedside devices. Similarly, ENSEMBLE users have a remote interactive capability to initiate recordings or printing of patient information and waveforms.

Vital signs and waveform information from up to 12 patients are be displayed simultaneously on an ENSEMBLE Central Station Monitor. Information from each individual patient is presented in a separate portion of the display. Each patient display area includes: Patient Name, Assigned Location (room), Primary Vital Sign Name, Value & Alarm Limits (nominally Heart Rate), Primary Waveform (nominally ECG), Secondary Vital Sign Numeric Data, Alarm Status Messages, and a dedicated "soft key" for recording waveforms. Software configurations allow more than one waveform or parameter to be displayed for each patient.

Primary operation of the ENSEMBLE is accomplished by a desktop mouse. A standard computer keyboard is used for manual entry of alphanumeric information. An optional touchscreen is available for users who prefer to use a touchscreen. Alternative "desktop devices", such as trackball and light pen, are also available as options. For large installations, with several ENSEMBLEs intended for a single user, the system may be configured to enable one keyboard and one mouse to control up to eight individual ENSEMBLE computers.

ENSEMBLE is a reusable, software driven, central station display terminal, 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. ENSEMBLE complies with UL 544, ANSI Safe Current Limits for Electromedical Apparatus, and FDA MDS-201-0004 voluntary standards. ENSEMBLE is not a kit, does not contain any drug or biological products and is for prescription use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Allen Schwebel, Ph.D.
Mennen Medical Ltd.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100
ISRAEL

Re: K970358
Ensemble Central Station Monitor
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: November 10, 1997
Received: November 13, 1997

Dear Dr. Schwebel:

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 (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/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

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.

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970358

Prescription ✓