November 15, 2023

Mennen Medical Ltd.
Erez Nimrod
Managing Director
Kiryat Weizmann Science Park
P.O. Box 102
Rehovot, 76100
Israel

Re: K020632
Trade/Device Name: Enguard Remote Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: QYX, DSI

Dear Erez Nimrod:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 15, 2002. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, Jennifer.Kozen@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Mr. Asher Kassel
Regulatory Affairs
Mennen Medical Ltd.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100
ISRAEL

Re: K020632
Trade Name: Enguard Remote Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: February 24, 2002
Received: February 27, 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 yours,

Bram. D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

*Enguard* is intended for use as a remote patient multiparameter monitoring system.

The *Enguard* 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 *Enguard 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 *Enguard* 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

Division of Cardiovascular, Respiratory Devices
510(k) Num K020632

MAR 1 5 2002

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

Date prepared: 24 February 2002

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92**
**Envoy Patient Monitor - Device Modification**
**Special 510k for Enguard Remote Patient Monitor**

**Establishment Name, Registration Number and Address**

| | |
|---|---|
| Name: | Mennen Medical Ltd. |
| Registration Number | 9611022 |
| Operator Number: | 9011766 |
| Address: | Kiryat Weizmann Science Park<br>Rehovot, 76100 Israel<br>Tel: 972-8-938-3030<br>Fax: 972-8-940-6519 |
| 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)

Proprietary: ENGUARD
Common: Remote Patient Monitor
Mennen Medical Part Number: 555-000-090

**FDA Classification**

| | |
|---|---|
| Classification Name: | Arrhythmia Detector and Alarm |
| Classification Number: | 21 CFR 870.1025 |
| Classification: | Class III |
| Product Code: | 74 DSI |

**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.

**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
- $eTCO_2$