K100127 1/2

Mortara

Abbreviated 510(k) Notification

APR 1 6 2010

510(k): ELI 230 Electrocardiograph Device Summary

Submitter: **Date: January 15, 2010**

Charles Morreale, Manager of Regulatory Affairs
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
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Contact: Charles Morreale (see above)

Trade Name: ELI 230 Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S.E. is claimed:

The Mortara Instruments ELI 230 Electrocardiograph is substantially equivalent to the legally marketed devices presently in distribution: Mortara Instrument ELI 250 Electrocardiograph (K031182).

Description:

The ELI 230 is a multi-channel diagnostic electrocardiograph intended for acquiring,viewing and printing ECG's of adult and pediatric patients. The ELI 230 utilizes previously cleared predicate Mortara technology and design features from the Mortara electrocardiograph device family, together with other current industry technologies, to achieve a highly reliable electrocardiograph. The device is not intended to be used as a vital signs physiological monitor. The ELI 230 is intended to be used by a licensed health care practitioner in a hospital or clinical setting.

The ELI 230 is a standard 12-lead, electrocardiograph that is intended to be used with the Mortara Wireless Acquisition Module (WAM) or Mortara Acquisition Module (AM12) patient cables. The ELI 230 acquires ECG waveforms from the WAM or AM12 patient cables.

The ELI 230 incorporates a similar user interface to that of the Mortara ELI 250 Electrocardiograph (K031182). The LCD on the ELI 230 is a QVGA color (320 x 240), 2.4" active matrix, TFT. Although slightly smaller than the ELI 250, the LCD displays waveforms as well as menus and configuration screens. As in the ELI 250, the user will use soft-keys to select functions displayed on screen: a group of five keys are available on the ELI 230 keyboard and they are located underneath the LCD. The ELI 230 implements the latest VERITAS™ Resting Interpretation criteria (adult/pediatric) (cleared in ELI 350 K082946).

The ELI 230 has a custom keyboard which includes symbol, cursor control and special function keys. The ELI 230 has a Main Configuration menu, divided in multiple pages, that includes all the default settings and user preferences (print speed, filters, etc.) The ELI 230 user will use soft-keys to select functions displayed on the LCD screen. A group of five keys and an On/Off key are available on the keyboard, and they are located near the LCD.

The ELI 230 prints on thermal roll paper oriented in the "landscape" mode. The printer is entirely controlled by software. When a print job is started the printer voltage is enabled, the 20 KHz chopper is enabled and the target speed is set. The 1 msec timer will step the motor phases every millisecond until the target speed is reached. ECG printout speed choices allowed are 5, 10, 25 and 50 mm/s. The outer dimensions of the ELI 230

are approximately 8 inches (width, left-to-right) x 12 inches (depth, front-to-back) x 3 inches (height, top-to-bottom). The housing of the ELI 230 is ABS polycarbonate. Provisions for mounting the ELI 230 to a cart will be made.

The ELI 230 operates from a standard AC connection and also has the capability of being operated directly from a sealed lead-acid battery. The battery is only removable / replaceable through disassembly of the unit. When operating from the battery, remaining charge will be monitored. When the battery charge is low, an indication will be made to the operator. When the battery charge is depleted to its lowest allowed level, the unit will automatically power down. The battery is charged by an internal power supply when connected to the AC line. The unit will indicate when the battery is being charged and when it has reached full charge. When the battery has been discharged to a pre-defined, low-voltage limit, the internal power supply will be capable of re-charging the battery to 90% of its full charge level within 8 hours.

Intended Use:

The ELI 230 is a multi-channel electrocardiograph product used for acquiring, viewing and printing resting ECG's. The ELI 230 is a 12-channel diagnostic electrocardiograph intended for recording and printing ECG's of adult and pediatric patients. The device is not intended to be used as a vital signs physiological monitor. The ELI 230 is intended to be used by a licensed health care practitioner in a hospital or clinical setting. It is designed to be used for acquiring, viewing and printing resting ECG's. The ELI 230 is a standard 12-lead, electrocardiograph that is intended to be used with the Mortara Wireless Acquisition Module (WAM) or Mortara Acquisition Module (AM12) patient cables.

Indications for Use:

The proposed Mortara ELI 230 Electrocardiograph is a non-invasive prescription device.

- The Mortara ELI 230 Electrocardiograph is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use for patients of any age, diseased or non-diseased.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. It is not intended as a sole means of diagnosis.
- The device is not intended to be used as a vital signs physiological monitor.
- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Mortara Instrument, Inc
c/o Mr. Charles Morreale
7865 North 86th Street
Milwaukee, WI 53224

Re: K100127
Trade/Device Name: Mortara ELI 230 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 15, 2010
Received: January 19, 2010

Dear Mr. Morreale:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K100127 1/1

Indications for Use

510(k) Number (if known): K100127

Device Name: **Mortara ELI 230 Electrocardiograph**

Indications for Use:

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- The device is not intended to be used as a vital signs physiological monitor.
- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100127

Concurrence of CDRH, Office of Device Evaluation (ODE)