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Mortara

Special 510(k): Device Modification

DEC 29 2008

510(k): ELI 350 Electrocardiograph Device Summary

Submitter:

Date: September 30, 2008

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Mortara Instrument, Inc.
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Milwaukee, WI 53224
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Contact: Charles Morreale (see above)

Trade Name: ELI 350 Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S. E. is claimed

The Mortara Instrument's ELI 350 Electrocardiograph is the next generation of the Mortara ELI 350 and is substantially equivalent to the legally marketed predicate device:

- ELI 350 by Mortara Instrument (K062677)

The proposed ELI 350 is a modification of the Mortara predicate device. It will combine enhanced capabilities with the current technology resulting in the next generation Mortara ELI 350 Electrocardiograph.

Description:

The ELI 350 is a multi-channel, high-end resting interpretation electrocardiograph. The ELI 350 simultaneously acquires data from up to 15 leads. Once the data is acquired, it can be reviewed, and/or stored, and/or printed.

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded from the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. The cardiac data acquired and provided by the ELI 350 is used by trained medical personnel to assist in the diagnosis of symptomatic patients with various rhythm patterns.

The ELI 350 is designed to be installed on a transport cart. Its design is a "clam-shell" style, with a 17" color LCD screen that can be closed over the printer when the unit is shipped or not in use. The ELI 350 is able to acquire, analyze, display and print electrocardiograms acquired through its internal Mortara front-end amplifier. The size of the screen will allow a full size preview of the record for the technician to assess the quality of the acquired ECG.

The ELI 350 uses a 17" SXGA (1280 x 1024 pixel) color LCD for display of ECG waveforms, menu options and status information. A full size keyboard is part of the ELI 350 design and allows patient data entry as well as control of the functions and options available for the unit. The ELI 350 custom keyboard will include alphabetic, numeric, symbol, cursor control and special function keys. The ELI 350 incorporates a full size thermal writer (8.5" x 11") that allows printouts using several formats available to the user, from the 6+6 channels to the Cabrera formats. The writer is also used by the unit for real time, continuous rhythm printout.

The ELI 350 will offer storage capability in order to retrieve or transmit stored records. Transmission can be achieved using one of the optional communication media designed in the unit: RS 232, LAN, WLAN, USB port, GSM module.

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Intended Use:

The ELI 350 is intended to be a high-performance, 15-lead, multifunctional electrocardiograph. As a resting electrocardiograph, ELI 350 simultaneously acquires data from 15 leads. Once the data is acquired, it can be reviewed and/or stored, and/or printed. It will be a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size.

Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- 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 on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2008

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

Re: K082946
Trade/Device Name: Mortara ELI 350 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 12, 2008
Received: November 14, 2008

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.

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. Y. Hillebrenner

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

Enclosure

Indications for Use

510(k) Number (if known): K082946

Device Name: Mortara ELI 350 Electrocardiograph

Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
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- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. S. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082946