Mortara

Abbreviated 510(k): Device Modification

DEC 14 2009

510(k): ELI 350 Electrocardiograph Device Summary

Submitter:

Date: August 20, 2009

Charles Morreale, Regulatory Affairs Manager
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 expands the capability of the Mortara ELI 350 and is substantially equivalent to the legally marketed predicate devices:

- ELI 350 by Mortara Instrument (K082946)
- X-Scribe Stress Exercise Testing System (K022618)
- MAC 5500 Resting ECG Analysis System (K073625)

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

Description:

ELI 350 Electrocardiograph

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 a multi-channel, high-end resting interpretation electrocardiograph utilizing a 17" SXGA (1280x1024 pixel) color LCD for display of ECG waveforms, menu options and status information. The LCD provides a preview of the record for the clinician to assess the quality of the acquired ECG. The overall design of the ELI 350 is a "clamshell" style where the LCD screen can be closed over the printer when the unit is shipped or not in use.

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 keyboard includes alphabetic, numeric, symbol, cursor control and special function keys. The ELI 350 is designed to be installed on a transport cart.

The ELI 350 is able to acquire data from up to 15-leads, analyze, display, and/or print electrocardiograms acquired via direct or wireless patient connection. The ELI 350 also offers 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, or GSM module.

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 printouts.

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The ELI 350 offers, adult and pediatric interpretation capability to assist the physician over-read of the electrocardiogram, review the electrocardiogram to identify the best 10 second sample based on noise, and will offer the options to conduct late potential analysis and allow connection to a treadmill or ergometer for exercise stress testing.

Stress Exercise Option

The ELI 350 Stress Exercise test option is a software module that can be loaded onto the ELI 350 platform. The Stress Exercise option allows the ELI 350 to function as a diagnostic tool to analyze, edit, review, report and store acquired ECG data of patients that have undergone stress exercise testing. The stress exercise software displays the electrocardiographic (ECG) waveforms, exercise time, ST measurements, and other data useful during testing utilizing stress test protocols for ergometer and treadmill.

The user is able to create test protocols that will be stored in the ELI 350 as well as to customize the display and printout formats. A final report will be generated and will offer editing capabilities of the final results as well as of the stored ECG events. The software will support the storage of final reports on a USB flash drive.

The cardiac data provided is reviewed, confirmed, and used by trained medical personnel to assist in the diagnosis of the electrocardiographic data reflecting the patient's physiological condition during stress exercise. The Stress Exercise test option expands the capabilities of the Mortara ELI 350 utilizing current technology.

Late Potential (Signal-averaged ECGs) Option

The Late Potential (Signal-averaged ECGs) option allows for the acquisition, analysis and printout of signal-averaged ECGs in order to detect ventricular late potentials. Late potentials are low amplitude, relatively high-frequency bioelectric signals which can be detected at the end of the QRS. When acquiring late potentials, orthogonal leads (X, Y, and Z leads are most commonly used).

Signal averaging techniques are used to calculate X, Y and Z averages. The averages will be combined and filtered into a filtered vector magnitude. The filtered vector magnitude will be used to measure QRSd, RMS40 and LAS40 and average noise level. The software will display and print these measurements along with the filtered vector magnitude. The software will support the storage of Late Potentials data on a USB flash drive.

Intended Use:

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

The stress exercise option is a diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data; creates summary tables, trends and a final report regarding a variety of cardiac data indices. The cardiac data provided is reviewed, confirmed, and used by trained medical personnel to assist in the diagnosis of the electrocardiographic data reflecting the patient's physiological condition during stress exercise testing.

The late potential, signal-averaged ECG (SAECG) option allows for the acquisition, analysis, and printout of signal-averaged ECGs in order to detect ventricular late potentials for consideration by a physician.

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.
- The device is indicated for use to acquire, analyze, display and print signal-averaged ECGs to detect ventricular late potentials for consideration by a physician.
- The device is indicated for use to acquire, process, record, archive, analyze, display and print ECG data of patients undergoing physiologic stress exercise testing.

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

Mortara Instrument, Inc.
c/o Mr. Charles Morreale
Regulatory Affairs Manager
7865 North 86th Street
Milwaukee, WI 53224 - 3431

DEC 14 2009

Re: K092663
Device Name: ELI 350 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: November 25, 2009
Received: December 8, 2009

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 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,

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): K092663

Device Name: **Mortara ELI 350 Electrocardiograph**

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- The device is indicated for use to acquire, process, record, archive, analyze, display and print ECG data of patients undergoing physiologic stress exercise testing.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092663