K102206

Abbreviated 510(k) Notification

FEB 18 2011

510(k): ELI 10 Electrocardiograph Device Summary

Submitter:

Date: November 18, 2010

Charles Morreale, Regulatory Affairs Manager
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
Fax: (414) 354-4760
Phone: (414) 354-1600
Contact: Charles Morreale (see above)

Trade Name: ELI 10 Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S. E. is claimed

The Mortara Instrument ELI 10 Electrocardiograph is the next generation of the Mortara ELI 10 and is substantially equivalent to the legally marketed predicate device:

- ELI 10 by Mortara Instrument (K070539)
- ELI 350 by Mortara Instrument (K082946)

The proposed ELI 10 is a modification of the Mortara predicate device. It will include the addition of Pediatric Criteria for the VERITAS™ Interpretive Algorithm and the ability to be utilized in a mobile environment (including pre-hospital, emergency medical services, ambulance and patient transport) with the current technology resulting in the next generation, Mortara ELI 10 Electrocardiograph.

Description:

The ELI 10 is a multi-channel, portable electrocardiograph. The ELI 10 simultaneously acquires data from up to 12 leads. Once the data is acquired, it can be reviewed, stored, transmitted and/or printed (using an external, optional printer).

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 10 is used by trained medical personnel to assist in the diagnosis of symptomatic patients with various rhythm patterns.

The ELI 10 is designed to be installed on a transport cart. The ELI 10 is able to acquire, analyze, display, transmit, print, record and store electrocardiograms acquired through its internal Mortara front-end amplifier. The size of the screen will allow preview of the record for the technician to assess the quality of the acquired ECG.

The ELI 10 utilizes a monochrome LCD for display of ECG waveforms, menu options and status information. A custom keyboard is part of the ELI 10 design and allows patient data entry as well as control of the functions and options available for the unit. The ELI 10 custom keyboard includes alphabetic, numeric, symbol, cursor control and special function keys. When an ECG is acquired, a preview will be displayed in this window. The ECG format used to display the waveforms will match with the configured printing format. Gain, speed and filter are applied to both screen and printout at the same time (Printing function available only through an external optional printer).

S1

The ELI 10 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: Modem, LAN, WLAN, GSM/GPRS, and/or USB port.

Intended Use:

The ELI 10 is intended to be a high-performance, multi-channel, multifunctional electrocardiograph. As a resting electrocardiograph, ELI 10 simultaneously acquires data from multiple channels. Once the data is acquired, it can be reviewed, stored, transmitted and/or printed. It will be a device primarily intended for use in hospitals, but may be used in mobile environments (including pre-hospital, emergency medical services, ambulance and patient transport), medical clinics and offices of any size.

Indications for Use:

- The device is indicated for use to acquire, analyze, display, transmit, print, record and store 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, or mobile environments (including pre-hospital, emergency medical services, ambulance and patient transport), 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.

Testing Performed and Summary Discussion:

The following testing was performed to support a determination of substantial equivalence for the ELI 10 Electrocardiograph: Medical Electrical Equipment – General Requirements for Safety, Electromagnetic Compatibility, Safety Requirements for Medical Electrical Systems, Particular Requirements for the Safety of Electrocardiographs and Protection Against Hazardous Output; Operating Temperature; Mobile Configuration Operating and Non-operating Vibration; Mobile Configuration Operating and Non-operating Shock; ECG Safe Current Limits for Electromechanical Apparatus; and ECG Performance.

The ELI 10 modification includes the capability for the addition of Pediatric Criteria for the VERITAS Interpretive Algorithm that was included within the cleared 510(k) Premarket Notification (K082946) and the ability utilize the ELI 10 within mobile environments (including pre-hospital, emergency medical services, ambulance and patient transport).

Approximately 1300 15-lead ECG's (standard 12 leads plus V3R, V4R and V7) were randomly collected in various pediatric cardiology centers. ECG's from this database were submitted to a cardiologist without automatic interpretation (blind reading) and in a standard 3x5 format at 10 mm/mV and 25 mm/s. The same ECGs were interpreted by the VERITAS Pediatric ECG Interpretation algorithm. The performance obtained by the algorithm is considered clinically acceptable. ELI 10 utilizes the same VERITAS Interpretive Algorithm as the ELI 350 (K082946).

The performance of the ELI 10 Electrocardiograph within a mobile environment has been successfully evaluated. The device therefore, performs as safety and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

FEB 18 2011

Re: K102206
Trade/Device Name: ELI 10 Electrocardiograph
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: December 27, 2010
Received: December 28, 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.

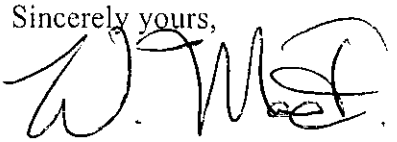
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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): K102206

Device Name: **Mortara ELI 10 Electrocardiograph**

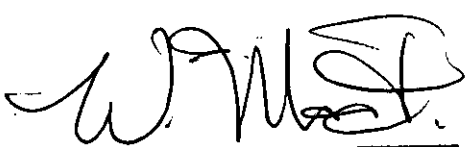
Indications for Use:

- The device is indicated for use to acquire, analyze, display, transmit, print, record and store 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, or mobile environment (including pre-hospital, emergency services, ambulance and patient transport), 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.

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 K102206