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Mortara

Special 510(k): Device Modification

MAR 15 2007

510(k): ELI 10 Electrocardiograph Device Summary

Submitter:

Date: February 20, 2007

Laura Spiegelhoff, Manager of Quality Assurance / Regulatory Affairs
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
Fax: (414) 354-4760
Phone: (414) 354-1600
Contact: Laura Spiegelhoff (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's ELI 10 Electrocardiograph is a current technology evolution of the Mortara EL-1 and is substantially equivalent to the legally marketed predicate device:

- EL-1 by Mortara Instrument (K851702)

The proposed ELI 10 is the evolutionary market replacement of this Mortara predicate device.

Description:

The proposed ELI 10 will be a multi-channel, portable electrocardiograph utilizing a 4" graphic LCD. The ELI 10 is a 12 lead resting interpretive electrocardiograph. The ELI 10 simultaneously acquires data from all 12 leads. Once the data is acquired, it can be reviewed, and/or stored, 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.

Intended Use:

The ELI 10 is intended to be a high-performance, multi-channel electrocardiograph. As a resting electrocardiograph, ELI 10 simultaneously acquires data from all 12 leads. Once the data is acquired, it can be reviewed and/or stored. It will be a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size.

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Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms. (Printing function available only through an external, optional printer.)
- 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 populations.
- The device is indicated for use on pediatric populations for acquisition, display, and printing of multi-channel ECGs.
- 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

APR - 5 2007

Mortara Instrument, Inc.
c/o Ms. Laura Spiegelhoff
Manager of Quality Assurance and Regulatory Affairs
7865 North 86th St.
Milwaukee, WI 53224-3431

Re: K070539
Trade/Device Name: ELI 10 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 20, 2007
Received: February 26, 2007

Dear Ms. Spiegelhoff:

This letter corrects our substantially equivalent letter of February 20, 2007.

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 (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

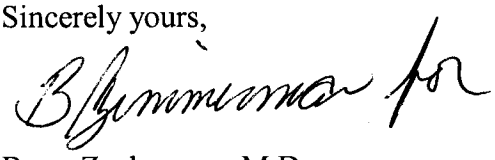
addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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 continue 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,



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

Indications for Use

510(k) Number (if known):_____

Device Name: **Mortara ELI 10 Electrocardiograph**

Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms. (printing function available only through an external, optional printer)
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- 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 K070539