K022618

510(k) Summary SEP 6 2002

Submitter:

Harlan Van Matre, *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: Harlan Van Matre (see above)

Trade Name: X-Scribe II

Common Name: Stress Exercise Testing System

Classification Name: Programmable Diagnostic Computer (Class II Per 21 CFR § 870.1425)
Electrocardiograph (Class II Per 21 CFR § 870.2340)

Legally marketed devices to which S.E. is claimed
Mortara X-Scribe Stress Exercise System – 510(k) K900720
Quinton Q-Stress – 510(k) K 001492

Description:

The Mortara X-Scribe II is the latest evolution of the Mortara X-Scribe (K900720). It is a PC based diagnostic tool consisting of an ECG analysis software application running on a commercial PC using Windows operating system. Electrocardiographic data is obtained by means of a compatible device, such as the Mortara X-12 (K974149) or the Mortara direct connect patient cable, and sent to the CPU for processing. The user may generate reports for display or may opt to print results via a printer.

The device consists of a CPU, display, mouse, printer, keyboard, isolation power supply, and data collector. The device may interface with external devices, including a treadmill or ergometer for dynamic exercise evaluation, non-invasive blood pressure equipment, and computer communications equipment.

Intended use:

The device is a PC based 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 by X-Scribe II 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.

Indications for use:

The device captures and presents electrocardiographic data reflecting a patient's physiological condition during physiologic stress testing that can be useful in determining a diagnosis when reviewed by a trained clinician or physician. The cardiac data provided by X-Scribe II is reviewed, confirmed, and used by trained medical personnel to assist in the diagnosis of adult patients with various rhythm patterns.

The device is not intended to be the sole basis of diagnosis.

The device is indicated for use in a clinical setting by a physician, or trained personnel who are acting on the orders of a licensed physician.

The device is indicated for use on adult populations, typically symptomatic.
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

SEP 6 2002

Mortara Instrument, Inc.
c/o Mr. Harlan L. Van Matre
Manager of Quality Assurance and Regulatory Affairs
7865 North 86th Street
Milwaukee, WI 53224-3431

Re: K022618
Trade Name: Mortara X-Scribe II Stress Exercise Testing System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: May 3, 2002
Received: August 7, 2002

Dear Mr. Van Matre:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K022618

Device Name: Mortara X-Scribe II Stress Exercise Testing System

The X-Scribe II is a PC based diagnostic tool intended to acquire, process, record, analyze, archive and output electrocardiographic data obtained during physiologic stress testing.

Intended use:

The device is a PC based 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 by X-Scribe II 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.

Indications for use:

- The device is indicated for use to acquire, process, record, archive, analyze, and output electrocardiographic data obtained during physiologic stress exercise testing.
- 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 device is indicated for use on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022618

Prescription Use X OR Over-The-Counter Use _____
(Per 21CFR801.109)

(Optional Format 1-2-96)