



Food and Drug Administration  
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January 6, 2016

Mortara Instrument, Inc.  
Ms. Eleanore Dias  
Regulatory Affairs Specialist  
7865 North 86th Street  
Milwaukee, Wisconsin 53224

Re: K152944

Trade/Device Name: Xscribe Stress Exercise Testing Systems, Q-stress Stress Exercise Testing Systems  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Electrocardiograph  
Regulatory Class: Class II  
Product Code: DPS, DQK  
Dated: December 11, 2015  
Received: December 14, 2015

Dear Ms. Dias:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

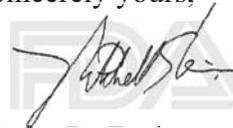
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

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)

K152944

Device Name

XScribe and Q-Stress Stress Exercise Testing System

Indications for Use (Describe)

The XScribe/Q-Stress device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing. The device is intended for use in adult, adolescent, and children patient populations. The device is intended for use in a clinical setting by trained personnel under the supervision of a licensed physician.

The device may interface with equipment for pulmonary function testing and other devices, including a treadmill or ergometer for dynamic exercise evaluation, as well as non-invasive blood pressure equipment, functional arterial oxygen saturation (SpO<sub>2</sub>) equipment, and computer communications equipment.

The device is not intended to be used as a vital signs physiological monitor.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Notification

## Section 5

### 510(k) Summary Statement

#### 1. Submitter

Mortara Instrument, Inc.  
7865 North 86<sup>th</sup> Street  
Milwaukee, WI 53224

Telephone 414-354-1600  
Fax 414-354-4760

#### Primary Contact

Eleanore Dias  
Regulatory Affairs Specialist  
eleanore.dias@mortara.com

#### Secondary Contact

Margaret Mucha  
Director of Global Regulatory  
Affairs  
meg.mucha@mortara.com

#### 2. Product Names

Device Trade Name	XScribe and Q-Stress
Common/ Usual Name	Stress Exercise Testing System
Classification	Programmable Diagnostic Computer
	870.1425 DQK Cardiovascular
	Electrocardiograph 870.2340 DPS Cardiovascular

**Note:** There are no previous submissions for this device



## Traditional 510(k) Notification

**3. Predicate Device to which this is Substantially Equivalent**

XScribe II

K022618

This predicate device has not been subject to a design-related recall

**4. Device Description**

The XScribe / Q-Stress device is a diagnostic device capable of real time ECG display, heart rate measurement, ST analysis and ventricular ectopic beat detection using wired or wireless acquisition modules. The device is able to generate risk scoring via recognized protocols. The device is capable of obtaining a resting ECG with automatic interpretation. The device can interface with equipment for pulmonary evaluation. The device has several built in exercise protocols for connection and control of exercise equipment such as treadmills and ergometers. The device supports measurement of non-invasive blood pressure. The device can output analog ECG signals or digital QRS trigger signals for synchronizing an external device. The device supports a touch screen interface as well as a keyboard / mouse interface and a wired remote control unit. The device will store a complete record of diagnostic quality test data from which the user can generate and review stress test reports. The device can function as standalone workstation or can connect via network to a database server allowing for remote review capabilities. The device can communicate with electronic record keeping systems to obtain work lists and patient data, and to provide test result reports.

**5. Intended Use**

The XScribe/Q-Stress device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing. The device is intended for use in adult, adolescent, and children patient populations. The device is intended for use in a clinical setting by trained personnel under the supervision of a licensed physician.



## Traditional 510(k) Notification

The device may interface with equipment for pulmonary function testing and other devices, including a treadmill or ergometer for dynamic exercise evaluation, as well as non-invasive blood pressure equipment, functional arterial oxygen saturation (SpO<sub>2</sub>) equipment, and computer communications equipment.

The device is not intended to be used as a vital signs physiological monitor.

### 6. Technological characteristics

The XScribe and Q-Stress Stress Exercise Testing System employs the same functional scientific technology as its predicate device XScribe II (K022618). At a high level, both devices employ a Windows based tool to acquire, process, record, archive analyze and record electrocardiographic data during physiologic stress testing. Both devices connect to treadmills, NIBP monitors, and ergometers.

XScribe/ Q-Stress was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. XScribe/Q-Stress is substantially equivalent to X-Scribe II (Predicate K022618) with the following technological differences:

- Added Cardiopulmonary function
- Added third party interface options through USB and serial ports for NIBP and SPO<sub>2</sub>
- Updated operating system to Windows 7
- Added Quinton Burdick treadmill compatibility
- Updated front end acquisition device to support the Wireless Acquisition Module (WAM) (K142105)
- Increased front end sampling rate
- Added report customization option
- Added DICOM communication protocol
- Added audit trails
- Added ability to import orders from EMR system
- Updated hardware to conform with EU Restriction of Hazardous Substances Directive
- Added remote keypad control of some features
- Added demonstration mode for training of clinicians
- Added ability for clinician to document drugs used during protocols
- Added Q-Stress user interface to XScribe software



## Traditional 510(k) Notification

A full comparison matrix of functionality is located in Section 12, Substantial Equivalence Discussion.

### **7. Determination of Substantial Equivalence – Non-clinical**

Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" and "*Off-the-Shelf Software Use in Medical Devices*."

XScribe/Q-Stress was designed and tested for compliance with the applicable clauses of the following standards:

- ANSI/AAMI ES60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance (2005 + C1:09 + A2:10)
- 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))
- IEC 60601-2-25 Medical electrical equipment - part 2-25: Edition 2.0 2011-10, particular requirements for the basic safety and essential performance of electrocardiographs. (Cardiovascular)

### **8. Determination of Substantial Equivalence – Clinical**

The subject of this premarket notification did not require clinical data to support substantial equivalence.

### **9. Conclusion**

The non-clinical data that supports the safety of this device as well as the hardware and software verification and validation that have been completed at the time of this submission demonstrate that XScribe/Q-Stress performs as intended. As a result of completed verification and validation activities to date, Mortara has determined the XScribe/Q- is substantially equivalent to the predicate device.