AUG 2 6 2008

II. 510(k) Summary K082173

A. Name of Device

Trade name:	Q-Stress and HeartStride
Common name:	Stress system
Classification name:	Electrocardiograph

B. Predicate Devices

Device Name	Premarket Notification
Q-Stress	K001492

C. Device description

Q-Stress and HeartStride are diagnostic devices capable of ECG monitoring; ST analysis and ventricular ectopic beat detection; generation, review, and storage of stress reports; and treadmill or ergometer control. These devices consist of a patient cable, preamplifier, PC, display, mouse, printer, keyboard, and isolation power supply. Approved serial devices such as non-invasive blood pressure measurement may be supported by these devices. Electrocardiographic data is obtained by the preamplifier and sent to the CPU for processing. The user may generate reports for display or may opt to print results via a printer.

The differences between the Q-Stress and HeartStride are as follows:

1. System Specifications/ Firmware
    a. HeartStride system specifications are the same as the Q-Stress. HeartStride could also be available as a software only product. The PC, monitor, mouse, and printer may be supplied by the customer, however, they must meet Cardiac Science Corporation (CSC) specifications.

    b. Q-Stress reports can be printed using chart recorder or laser printer. However, HeartStride reports can only be printed using laser printer.

c. Remote keypad and external hard drive are available with Q-Stress, but not with HeartStride.

2. Software
   a. HeartStride has a different toolbar and provides a testing wizard.
   b. Different options are available with the Q-Stress and the HeartStride device.

Q-Stress:

- Network
- Q-Exchange (includes Q-Exchange+)
- Full Disclosure
- Freeze Frame
- Risk Scoring
- Re-analysis
- Ramped Protocol Generator
- Custom Reports
- SpO2
- Interface to TMX425

HeartStride:

- Network
- Q-Exchange (does not include Q-Exchange+)
- QRS sync and Analog outs
- Interface to TMX425

D. Intended use

The device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing. 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. The device is intended for use in a clinical setting by trained personnel under the supervision of a licensed physician. The device is intended for use in adult populations, typically symptomatic. The device is not intended to be used as a vital signs physiological monitor.

E. Summary

The intended use, indication for use, and principle of operation are substantially equivalent to the predicate devices. We believe that the modifications to the device do not raise any new questions of safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2008

Cardiac Sciences Corporation
c/o Ms. Beverly Magrane
Senior Manager RA/RC
3303 Monte Villa Parkway
Bothell, WA 98201-8969

Re: K082173
Trade/Device Name: Q-Stress and HeartStride
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 30, 2008
Received: August 1, 2008

Dear Ms. Magrane:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

I. Indications for Use Statement K082173

510(k) Number: TBD

Device Name: Q-Stress and HeartStride

Indications for Use:

The device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing. 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. The device is intended for use in a clinical setting by trained personnel under the supervision of a licensed physician. The device is intended for 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 NECESSARY)
Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082173