MAR 2 8 2006

K052898

This 510(k) Summary is prepared in accordance with 21 CFR 807.92.

1. BASIC INFORMATION

1.1 SUBMITTER

Name:	Brentwood Medical Technology Corp.
Address:	3300 Fujita Street Torrance, CA 90505
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Preparation Date:	January 17, 2006

1.2 DEVICE NAME

The trade name and the proprietary name of the device is the *IQmark EZ Stress*. (The remainder of this submission refers to the device as the "*IQmark EZ Stress*"). The common name of the device is Stress Test System. Classification names and Product Classification Codes are as follows:

Classification	Code	Description
870.2340, II	DPS	Electrocardiograph
870.2340, II	MLC	Non-alarming ST Segment Monitor
870.2300, II	DRT	Cardiac Monitor(including cardiotachometer and rate alarm)

1.3 IDENTIFICATION OF LEGALLY MARKETED DEVICE

Substantial equivalence is claimed to a legally marketed device cleared under the names:

1) Q-Stress. Quinton Instrument Inc. 510(k) Number: K001492.
2) CASE 8000 exercise testing system. GE Medical Systems. 510(k) Number: K991014.

1.4 DEVICE DESCRIPTION

The block diagram below shows the overall configuration of a stress testing system using the *IQmark EZ Stress* software.

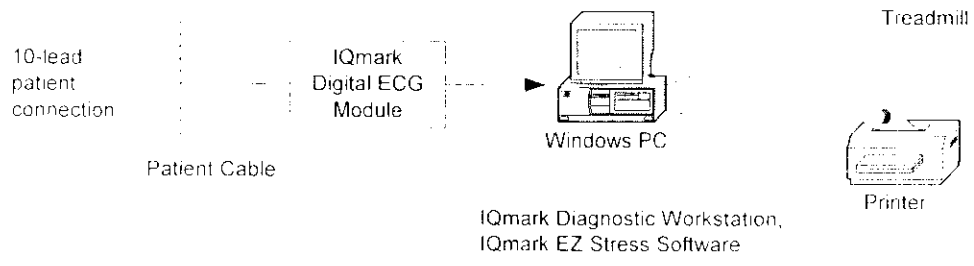

Figure 1. *IQmark EZ Stress* test system configuration

The *IQmark EZ Stress* test system is a computer-based diagnostic electrocardiograph that is designed for exercise stress test. The IQmark stress runs on the Microsoft Windows environments and can control a treadmill or an ergometer through a serial port. The *IQmark EZ Stress* provides real time ECG data acquisition, waveform display, and QRS detection. It calculates the heart rate, detects ventricular ectopic beats, generates the average beats, measures the ST segment levels and slopes, generates the test reports, and stores the reports in the database. The *IQmark EZ Stress* system also provides reports and ECG strip printing and review and editing capabilities for trained personnel to manage the patient's report.

The *IQmark EZ Stress* test system uses the same ECG data acquisition hardware as the IQmark Digital ECG (formerly Brentwood PCECG, 510K number: K955023). The ECG devices have been in market for more than 7 years. The QRS detection and ST analysis algorithm used in the *IQmark EZ Stress* is derived from Brentwood Real Time ST and Arrhythmia Analysis Software Library (STAR) (510K number: K013717).

1.5 Intended Use

The *IQmark EZ Stress* is intended to be used under the supervision of a physician, in hospitals, clinics and physician's office, to acquire, display, process, record, analyze and print the patient's electrocardiograms from the human body surface during stress induced from exercise devices such as a treadmill, a bicycle ergometer or drug induced (pharmacological) stress.

The device may provide interfaces with external devices, such as a treadmill or an ergometer, non-invasive blood pressure equipment, and computer communication equipment.

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

1.6 Comparison to Cleared Device

The *IQmark EZ Stress* device and the predicate devices have equivalent indications for use, intended use environment, and technical specifications and features. Table 1 compares the indications for use and intended use environment. Table 2 compares the technical specifications and features of the proposed device to the predicate devices.

Table 1: Indications For Use Comparison of IQmark EZ Stress to Predicate Devices

Indications for Use	IQmark EZ Stress	CASE 8000 (K991014)	Q-Stress (K001492)
Intended Use	To acquire, display, process, record, analyze and print the patient's electrocardiograms from the human body surface during stress induced from exercise devices such as a treadmill, a bicycle ergometer or drug induced (pharmacological) stress. Not intended to be used as a vital signs physiological monitor.	To acquire, process, record, archive, analyze, and output data during a period of physiologic stress or during a resting ECG condition. Not intended to be used as a vital signs physiological monitor.	To acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing. Not intended to be used as a vital signs physiological monitor.
Interface With External Devices	May provide interfaces with external devices, such as a treadmill or an ergometer, non-invasive blood pressure equipment, and computer communication equipment.	Treadmill or ergometer and communications with centralized electronic/ digital storage system.	Treadmill or ergometer for dynamic exercise evaluation, non-invasive blood pressure equipment, and computer communications equipment.
Intended Use Environment	Under the supervision of a physician, in hospitals, clinics and physician's office	Hospital based exercise testing laboratories, but can be used in clinics, physician offices, outreach centers or wherever exercise testing is performed.	Clinical setting by trained personnel who are acting on the orders of a licensed physician
Patient Population	Not specified	Not specified.	Adult populations, typically symptomatic

Table 2: Technical Specifications and Features Comparison of IQmark EZ Stress to Predicate Devices

Feature	IQmark EZ Stress	CASE 8000 (K991014)	Q-Stress (K001492)
Microsoft Windows Operating Systems	Yes	Yes	Yes
Computer communication and data storage (network)	Optional	Optional	Optional
Maximum ECG leads	12	15	12
ECG analysis frequency	500Hz	500Hz	Not specified
ECG frequency response (-3 dB)	0.05-150Hz	0.01-150Hz	Not specified
High pass filter	0.05Hz	0.01Hz	Not Specified
Low pass filter	40, 150Hz	20, 40,100,150Hz	Not specified
Line Filter	50, 60Hz	50, 60Hz	50, 60Hz
Baseline correction	Yes	Yes	Yes
CRT ECG display	3/6/12 configurable	3/6/12 configurable	3/6/12 configurable
ECG display speed	12.5, 25, 50 mm/sec	25, 50 mm/sec	5,25,50 mm/sec
Average beat display	Yes	Yes	Yes
Real time QRS detection and heart rate display	Yes	Yes	Yes
Ectopic beat detection and display	Yes	Yes	Yes
ST measurements (ST level, ST slope) based on average beat	Yes	Yes	Yes
J and post-J point	Manual or computer selected	Manual or computer selected	Manual or computer selected
ST trending	Yes	Yes	Yes
Automatic treadmill control interface	Yes	Yes	Yes
Standard and customizable exercise protocols	Yes	Yes	Yes
Average beat summary report, rhythm strip report	Yes	Yes	Yes
Reanalysis	Yes	Yes	Yes
12-lead Resting ECG Analysis	Yes	Yes	Yes
Pacemaker analysis (Resting ECG)	Yes	Yes	No

Table 2 demonstrates that the proposed *IQmark EZ Stress* has many identical or similar technical specifications and features to the two predicate devices. They all run on Microsoft Windows with IBM compatible PC, use maximum 12 or more ECG leads, have similar signal processing capabilities, can detect QRS wave (and heart rate), and can perform ST segment measurements. They also have similar editing and report generating functionalities. The technical specifications and features listed in Table 2 and in the product specification documents of the *IQmark EZ Stress* have been verified and validated. The feature comparison in Table 2 and the verification and validation results

demonstrated that the *IQmark EZ Stress* system is as safe, as effective, as the two predicate devices.

2. DEVICE SAFETY AND EFFECTIVENESS

The *IQmark EZ Stress* System Risk Analysis document identified the potential patient safety hazards associated with use of the Stress Test. The document also identified the risk reduction activities whose correct implementation must be validated to ensure safety. The Software Validation Procedure prescribed Traceability Analysis as the method to ensure the implementation of those risk reduction activities. The Software V&V Report contains a copy of the Traceability Analysis report, which demonstrates the implementation of the prescribed risk reduction activities. The Risk Analysis document concludes that the *IQmark EZ Stress* is a safe device if the prescribed risk reduction activities are implemented.

The *IQmark EZ Stress* uses the same ECG data acquisition hardware as the IQmark Digital ECG (formerly Brentwood PCECG, 510K number: K955023). The ECG hardware is designed in conformance with the AAMI/ANSI EC11: 1991 and meets the EMC requirements of the EN60601-1-2 :2001. The QRS detection, heart rate calculation, and ST segment measurement algorithms are delivered from Brentwood's ST and Arrhythmia Analysis library (510K number: K013717). The performance of the heart rate calculation and ST segment measurements are also tested according to the appropriate sections of the AAMI/ANSI EC13: 1992 and AAMI/ANSI EC38: 1998.

In conclusion, our test results have demonstrated that the *IQmark EZ Stress* is as safe and as effective as the two predicate devices.

3. VERIFICATION AND VALIDATION TEST

Verification and validation tests were performed for the entire development effort. A Software Verification Procedure was created and executed to confirm that the software development effort was performed as planned and to prescribe testing to challenge the correct implementation of the design. A software Validation Procedure was created and executed to challenge the completeness and correctness of the implementation of the user level requirements specified by the Software Requirements Specification and to confirm the implementation of the risk reduction activities prescribed by the System Risk Analysis. The *IQmark EZ Stress* has also undergone beta tests in a physician's office.

The results of execution of the test procedures and the beta tests are described in the Software Verification and Validation Report. The test results have demonstrated that the *IQmark EZ Stress* meets its design specifications and is as safe and as effective as the two predicate devices. Q-Stress by Quinton Instrument, and CASE 8000 by GE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Brentwood Medical Technology Corp.
c/o Mr. Neil E. Devine
Intertek Testing Services NA, Inc.
70 Codman Hill Rd.
Boxborough, MA 01719

Re: K052898
Trade Name: IQMark EZ Stress
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: March 09, 2006
Received: March 10, 2006

Dear Mr. Devine:

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 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 (301) 443-6597 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

Indications for Use

510(k) Number (if known): _____

Device Name: IQmark EZ Stress

Indications for Use: IQmark EZ Stress is intended to be used under the supervision of a physician, in hospitals, clinics and physician's office, to acquire, display, process, record, analyze and print the patient's electrocardiograms from the human body surface during stress induced from exercise devices such as a treadmill, a bicycle ergometer or drug induced (pharmacological) stress.

The device may provide interfaces with external devices, such as a treadmill or an ergometer, non-invasive blood pressure equipment, and computer communication equipment.

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

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (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 K052898