K013717

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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
Contact Person:	Ruomei Zhang, PhD
Phone Number:	(310) 530-5955 x7210
Preparation Date:	November 6, 2001

1.2 DEVICE NAME

The name of the device is the *Brentwood Real Time ST and Arrhythmia Analysis Software Library.*

The classification name is "Arrhythmia detector and alarm".

The common/usual name is "Patient Monitor".

1.3 IDENTIFICATION OF LEGALLY MARKETED DEVICE

Substantial equivalence is claimed to a legally marketed device cleared under the name, "ST/AR ST and Arrhythmia Software, Release D.0". The registered manufacturer of the cleared device is Agilent Technologies, Inc. of Andover, MA, and the 510(k) number is K003621.

1.4 DEVICE DESCRIPTION

The *Brentwood Real Time ST and Arrhythmia Analysis Software Library* is an "object library". An object library is a collection of callable functions that have been compiled (or assembled) into the native machine code of the computer on which they will execute. An application software program can be written to invoke some or all of the functions in an object library. The compiled (or assembled) application code can be "linked" to the called functions from an object library at the time the executable code image is built. An executable code image created in this manner will contain the application software code and all of the functions it invoked from the object library.

The *Brentwood Real Time ST and Arrhythmia Analysis Software Library* consists of a collection of ANSI Standard C (ISO/IEC 9899) callable functions. It provides real time ECG signal processing, QRS detection, QRS complex feature extraction, ventricular ectopic beat detection, ST level measurement, rhythm calls, and ventricular fibrillation detection capabilities for up to 12 leads of captured ECG lead data.

Brentwood will compile the *Brentwood Real Time ST and Arrhythmia Analysis Software Library* using the compiler specified by an ECG analysis device manufacturer. An object library will be created and delivered to the manufacturer, who can then integrate it into application software for their ECG analysis device(s).

1.5 INTENDED USE

The intended user of the *Brentwood Real Time ST and Arrhythmia Analysis Software Library* user is a medical device manufacturer who will integrate it into a computerized device that analyzes ECG signals captured from the human body surface. The library will provide the device with real time ECG signal processing, QRS detection, QRS complex feature extraction, ventricular ectopic beat detection, ST level measurement, rhythm calls, and ventricular fibrillation detection capabilities. The intended user is expected to label the device for use only by or under the supervision of a trained physician. The intended user is further assumed to have a quality system for developing and implementing software. The quality system should call for validating software, including the use of purchased software.

1.6 COMPARISON TO CLEARED DEVICE

Both the *Brentwood Real Time ST and Arrhythmia Analysis Software Library* and the predicate are software only devices that monitor cardiac function. Table 1 compares the features of the Brentwood device to the predicate.

Table 1: Comparison of Brentwood's ST/AR Library to Predicate Device

Feature	Agilent	Brentwood
heart rate determination for (paced and non-paced) adult, pediatric, and neonatal patients	yes	yes
(non-paced) ventricular arrhythmia calls for adult, pediatric, and neonatal patients	yes	yes
(non-paced) ST segment level measurement for adult patients	yes	yes
(non-paced) ventricular ectopic beat detection	yes	yes

2. PERFORMANCE TESTING

The following testing was performed in accordance with ANSI/AAMI EC57:1998 to evaluate the performance of the *Brentwood Real Time ST and Arrhythmia Analysis Software Library*. Unless otherwise noted, all testing used the AHA, MIT-BIH, and NST standard databases:

- accuracy of QRS detection,
- accuracy of heart rate measurement,
- accuracy of VEB detection,
- ventricular fibrillation (also CU database),
- ST segment analysis (ESC database only)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Ruomei Zhang, Ph.D.
Chief Technical Officer
Brentwood Medical Technology Corp.
3300 Fujita Street
Torrance, CA 90505

Re: K013717
Trade Name: Brentwood Real Time ST and Arrhythmia Analysis Software Library (ST/AR Library)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: November 6, 2001
Received: November 8, 2001

Dear Dr. Zhang:

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.

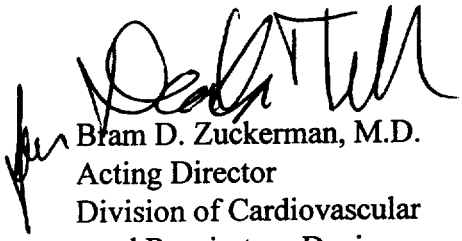
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K013717

Device Name

Brentwood Real-Time ST and Arrhythmia Analysis Software Library (referred to as the *ST/AR Library*).

Indications for Use

The intended user is a medical device manufacturer who will integrate the *ST/AR Library* into a computerized cardiac monitoring device. The manufacturer/integrator will ultimately identify the indications for use, depending on the nature of their device.

The analysis capabilities of the *ST/AR Library* are indicated for monitoring and detecting the following from up to 12 body surface ECG leads for adult, pediatric, or neonatal patients:

- QRS detection
- ventricular ectopic beat detection (non-paced only)
- rhythm call analysis, including asystole, bigeminy, couplets, irregular heart rate, pause or missed beat, VEB/minute, run, trigeminy, triplets, ventricular tachycardia
- ST segment level measurement (adult patients only)
- ventricular fibrillation detection

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE TO ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013717

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