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510(k) Summary of Safety and Effectiveness

510(k) Notification
Date: August 4, 2006
January 3, 2007 Revised
March 6, 2007 Revised

MAR 2 2 2007

Submitter:
Monebo Technologies, Inc.
1800 Barton Creek Blvd
Austin, Texas 78735-1606

Contact Person:
Dale J. Misczynski
Phone: 512-732-0235
Fax: 512-732-0285
Email: dale.misczynski@monebo.com

Trade/Device Name: Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS

Level of Concern Statement

The Monebo Automated ECG Analysis and Interpretation Software Library is a Moderate Level of Concern Software Device.

The library is intended for use with ECG management software which is a Moderate Level of Concern software device.

The library is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

A latent design flaw, failure or malfunction of the software, which were not revealed during the validation, verification and testing process, is possible over the life of the product. The results could result in a delayed response of appropriate medical care that would lead to injury or further diagnostic evaluations. The intended end users of the ECG analysis information are trained medical professional who are responsible for reviewing the device output and rendering the final diagnostic or treatment decision.

Predicate Devices:

The Monebo Automatic Arrhythmia Detection Software Library, Agilent and Brentwood predicates are software only devices that monitor cardiac function. Table 1 compares the features of the Monebo Automated ECG Analysis and Interpretation Software Library to predicate devices.

Feature	Monebo Automated ECG Analysis and Interpretation Software Library	Monebo Automatic Arrhythmia Detection Software Library 510(k) K043380	Agilent 510(k) K003621	Brentwood 510(k) K013717
Heart rate determination for non-paced adult	YES	NO	YES	YES
QRS Detection	YES	YES	YES	YES
Non-paced arrhythmia interpretation for adult patients	YES	NO	YES	YES
Non-paced ventricular arrhythmia calls for adult patients	YES	YES	YES	YES
Intervals measurement	YES	NO	YES	YES
Ventricular ectopic beat detection	YES	YES	YES	YES
Patient Populations	Adult	Adult	Adults, Pediatric, Neonatal	Adult

Test Results

The bench test results of the software using AHA and MIT-BIH databases per ANSI/AAMI EC 57 are shown in the table below:

Summary results of AHA and MIT testing				
Database	**QRS Se**	**QRS +P**	**VEB Se**	**VEB +P**
AHA	99.56	99.9	82.49	95.65
MIT-BIH	99.45	99.45	87.03	87.76
NST	91.56	85.66	81.79	53.19

The bench test results of the software using CSE database per IEC 60601-2-51 are shown in the tables below:

Summary results of CSE DB testing				
Measurement	**Acceptable Mean difference**	**Acceptable standard deviation**	**Monebo mean difference**	**Monebo standard deviation**

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PR interval	±10	±10	-8.8	10
QRS duration	±10	±10	0	10
QT interval	±25	±30	1.5	26

Summary results of MIT DB arrhythmia statement testing:

Accuracy of Arrhythmia Detection			
Sensitivity	**Specificity**	**Positive Predictive Accuracy**	**Negative Predictive Accuracy**
96	97	73	97
Arrhythmias: Normal sinus rhythm, Sinus Bradycardia, Sinus Tachycardia, PVC, APC, Atrial Fibrillation, Ventricular Tachycardia, Ventricular Flutter, Sinus Tachycardia, Pause (Asystole), AV block, BBB, Ventricular trigeminy, Ventricular Bigeminy, AIVR			

Accuracy of Arrhythmia Statements				
Arrhythmias	**Sensitivity**	**Specificity**	**Positive Predictive Accuracy**	**Negative Predictive Accuracy**
MIT DB				
Normal sinus rhythm	100	100	95	100
PVC	100	100	86	100
APC	96	66	70	66
Atrial Fibrillation	100	100	77	100
Ventricular Tachycardia	75	89	60	89
Bradycardia	Insufficient data	96	Insufficient data	96
Tachycardia	Insufficient data	100	Insufficient data	100
AV block	57	87	26	87
BBB	77	88	25	88
Ventricular Trigeminy	50	84	100	84
Ventricular Bigeminy	81	93	81	93
AIVR	100	100	15	100
Pause	Insufficient data	Insufficient data	Insufficient data	Insufficient data
CU DB				
Ventricular Flutter*	100	94	*	*
** Positive Predictive and Negative Predictive Accuracy cannot be calculated because all records contain VF*				

The results covering Sensitivity, Positive Predictivity, Specificity, False Positive Rate, and Negative Predictivity and which are based on a database of 250 annotated ECG strips recorded by various event recorders are in the table below.

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Rhythm	Sensitivity	Positive Predictivity	Specificity	False Positive Rate	Negative Predictivity
	Se	+P	Sp	FPR	-P
Normal sinus rhythm	91.18	100.00	100.00	0.00	96.81
Atrial fibrillation	90.91	80.00	95.15	4.85	98.00
Nodal rhythm	76.47	46.43	93.56	6.44	98.20
SVTA	100.00	61.90	92.86	7.14	100.00
Ventricular tachycardia	100.00	85.71	99.59	0.41	100.00
BBB	82.14	79.31	97.30	2.73	97.74
1st degree AV block	88.46	74.19	96.43	3.57	98.63
2nd degree AV block (Mobitz 1)	96.77	100.00	100.00	0.00	99.55
2nd degree AV block (Mobitz 2)	100.00	100.00	100.00	0.00	100.00
Complete AV block	96.77	100.00	100.00	0.00	99.55
Idioventricular rhythm	72.73	88.89	99.58	0.42	98.76
Sinus bradycardia	91.67	100.00	100.00	0.00	98.62
Sinus tachycardia	77.78	100.00	100.00	0.00	98.31
APC	77.50	65.26	80.59	19.41	88.39
PVC	89.55	73.17	87.98	12.02	95.83
Pause	96.88	73.81	94.95	5.05	99.52
Overall Performance	**90.23**	**82.19**	**96.42**	**3.58**	**98.23**

Device Description:

The Monebo Automated ECG Analysis and Interpretation Software Library is an "object library". An object library is a collection of callable functions that have been complied (or assembled) into machine code or IDL code of the computer on which they execute. The Monebo Automated ECG Analysis and Interpretation Software Library consists of a basic application for viewing, analyzing and annotating ECG data, and a callable object library built on the Microsoft™ .Net framework. An application software program can be written to invoke some or all of the functions in an object library.

The Monebo Automated ECG Analysis and Interpretation Software Library provides ECG signal processing, QRS detection and measurement of duration, QRS feature extraction, classification of Normal and Ventricular Ectopic beats, heart rate measurement, measurement of PR and QT intervals, and rhythm interpretation for up to 16 leads of captured ECG data.

The library can be accessed through an Application Program Interface (API) as a callable function. This allows the library to be used as an accessory to an ECG management application or as a stand-alone product.

Monebo will compile the Monebo Automated ECG Analysis and Interpretation Software Library specified by an ECG device manufacturer. An object library will be created and delivered to the device manufacturer, who can then integrate it into application software for their ECG analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2007

Monebo Technologies Inc.
c/o Mr. Dale Misczynski
1800 Barton Creek Blvd
Austin, TX 78735

Re: K062282
Trade/Device Name: Monebo Automated ECG Analysis and Interpretation Software Library
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 6, 2007
Received: March 7, 2007

Dear Mr. Misczynski:

This letter corrects our substantially equivalent letter of March 22, 2007.

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 (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 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 continue 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 (240) 276-3150 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

Indications for Use

510(k) Number: K062282

Device Name: Monebo Automatic ECG Analysis and Interpretation Software Library

Indications for Use:

The Automatic Analysis and Interpretation Software Library is intended for use by qualified medical professionals for the assessment of arrhythmias using historic ambulatory ECG data. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, Event Monitor, 12 lead ambulatory or resting ECG devices, or other similar devices when assessment of the rhythm is necessary. The Automatic Analysis and Interpretation Software Library can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. The Automatic Analysis and Interpretation Software Library provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for up to sixteen(16) leads of captured data. The library is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices

The product can be integrated into computerized ECG monitoring devices. In this case the medical device manufacturer will identify the indication for use depending on the application of their device.

Prescription Use __√____ AND/OR Over-The-Counter Use _____

(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 K062282