**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

Zywie, Inc.
% Jon Ward
President and CEO
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, Florida 33572

Re: K142693
Trade/Device Name: ZywieAI Software Library
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 12, 2015
Received: January 13, 2015

Dear Jon Ward,

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,

Melissa A. Torres -S

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): K142693

Device Name: ZywieAI Software Library

The ZywieAI 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, MCT (Mobile Cardio Telemetry), or other similar devices when assessment of the rhythm is necessary. The ZywieAI Software Library can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as ECG management system. The software library provides ECG signal processing and analysis on a beat by beat basis, QRS Detection, Non-paced Arrhythmia Interpretation, PAC (Premature Atrial Contraction), Non-paced Heart Rate determination, Pause, Tachycardia, Bradycardia, Atrial Flutter/Fibrillation, Ventricular Flutter/Fibrillation, Ventricular Ectopic Beat detection, Ventricular Tachycardia, AV (Atrioventricular) Conduction Block, ST Change Episode detection, and Non-paced Ventricular Arrhythmia calls.

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.

The product cannot be used with potentially life-threatening arrhythmias which require inpatient monitoring.

Verification of the output from ZywieAI Software is the responsibility of a trained healthcare professional or physician.

The ZywieAI Software Library is used for analyzing ECG data for adult patient population.

| | | |
|---|---|---|
| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use<br>(21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) SUMMARY
# (as required by 807.92)

## I. SUBMITTER

Zywie, Inc.
12000 Findley Road, Suite 360
Johns Creek, GA 30097

Phone: 678-992-1941
Fax: 678-230-9196

Contact Person: Latha Ganeshan
Date Prepared: September 19, 2014

## REGULATORY CORRESPONDENT

AJW Technology Consultants, Inc
445 Apollo Beach, Blvd
Apollo Beach, FL 33572

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Jon Ward, President
Email: wardjp@ajwtech.com

## II. DEVICE

**Name of Device:** ZywieAI Software Library
**Common or Usual Name:** Automated ECG Analysis and Interpretation Software
**Classification Name:** Electrocardiograph
**Device Panel:** Cardiovascular
**Regulatory Class:** II
**Product Code:** DPS

## III. PREDICATE DEVICE

The ZywieAI Software Library is substantially equivalent in intended use and similar technological characteristics of Monebo Automatic ECG Analysis and Interpretation Software Library cleared as part of K062282 and the IQmark Digital Holter which was cleared under K031466.

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission

## IV. DEVICE DESCRIPTION

The ZywieAI Software Library is an "object library". An object library is a collection of callable functions that have been compiled (or assembled) into machine code or Interactive Data Language (IDL) code for the computer on which they execute.

The basic software application reads the input ECG signals from a file into computer memory and passes that data to ZywieAI Software Library for analyzing, annotating, and creating output. This output is sent back to the basic software application where the output is written to a file. The read input signal may invoke some or all of the functions in the object library. An application program could be written to write input data to a file using web services. The same or a different application program could be written to consume the output file using web services.

The ZywieAI Software Library provides ECG signal processing, QRS Detection, Non-paced Arrhythmia Interpretation, PAC, Non-paced Heart Rate determination, Pause, Tachycardia, Bradycardia, Atrial Flutter/Fibrillation, Ventricular Flutter/Fibrillation, Ventricular Ectopic Beat detection, Ventricular Tachycardia, AV Conduction Block, ST Change Episodes detection, Non-paced Ventricular Arrhythmia calls and rhythm interpretation.

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

Zywie will compile the ZywieAI Software Library as 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. Typically the software library is used along with ECG monitoring devices and ECG management software for patients:

- With symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
- With palpitations with or without know arrhythmias to obtain correlation of rhythm with symptoms.
- Who require monitoring effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
- Recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring
- With diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
- Requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter
- With co-morbid conditions such as hyperthyroidism or chronic lung disease

## V. INDICATIONS FOR USE

The ZywieAI 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, MCT (Mobile Cardio Telemetry), or other similar devices when assessment of the rhythm is necessary. The ZywieAI Software Library can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as ECG management system. The software library provides ECG signal processing and analysis on a beat by beat basis, QRS Detection, Non-paced Arrhythmia Interpretation, PAC (Premature Atrial Contraction), Non-paced Heart Rate determination, Pause, Tachycardia, Bradycardia, Atrial Flutter/Fibrillation, Ventricular Flutter/Fibrillation, Ventricular Ectopic Beat detection, Ventricular Tachycardia, AV (Atrioventricular) Conduction Block, ST Change Episode detection, and Non-paced Ventricular Arrhythmia calls.

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.

The product cannot be used with potentially life-threatening arrhythmias which require inpatient monitoring.

Verification of the output from ZywieAI Software is the responsibility of a trained healthcare professional or physician.

The ZywieAI Software Library is used for analyzing ECG data for adult patient population.

## VI. COMPARISON OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The monitoring of basic physiological parameters is the technological principle for both the subject and predicate devices. At a high level, the subject and predicate devices are based on the following same technological characteristics:

**K062282 – Monebo Automated ECG Analysis and Interpretation Software**

- Read raw ECG signal data and analyze
- device algorithms are proprietary software library and are server based

**K031466 – IQmark Digital Holter**

- device algorithms are proprietary software library and are server/pc based

The following technological differences exist between the subject and predicate devices:

**K062282 – Monebo Automated ECG Analysis and Interpretation Software**

- Predicate device doesn't have the ST segment change detection capabilities
- The predicate device reports "Insufficient data" for Pause, Tachycardia, and Bradycardia, whereas subject device testing was done using sufficient data from the MITDB (The MIT-BIH Arrhythmia Database), NSTDB (The MIT-BIH Noise Stress Test Database), QTDB (The QT Database – PhysioNet) & ESCDB (The European ST-T Database – PhysioNet)databases. Positive and Negative Predicative Accuracy cannot be calculated for Ventricular Flutter/Fibrillation because all records contain VF

**K031466 – IQmark Digital Holter**

- Predicate device doesn't have the QRS Detection, PAC, Tachycardia, Bradycardia Atrial and Ventricular Flutter/Fibrillation, Ventricular Tachycardia, AV Conduction Block, Non-paced Ventricular Arrhythmia calls capabilities

## VII. PERFORMANCE DATA

The following performance date were provided in support of the substantial equivalence determination

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could directly result in minor injury to the patient or operator.

**Reference Standards**

The ZywieAI Software Library meets the requirements of following performance standards in accordance with FDA Guidance for the content of Premarket Submission for Software Contained in Medical Devices Document for Class II Moderate Level of Concern:

- ANSI/AAMI EC57:20012 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
- IEC 62304:2006 Medical device software – Software lifecycle processes

## VIII. CONCLUSIONS

The testing completed demonstrates that the ZywieAI Software Library exhibits comparable technical and functional characteristics to the predicate devices.

Based on those characteristics, the ZywieAI Software Library is substantially equivalent to the predicate device in safety and effectiveness in addition to being intended for the same uses.