January 28, 2019

ZOLL Manufacturing Corporation
Zachary Nelson
Sr. Regulatory Affairs Manager
2000 Ringwood Avenue
San Jose, California 95131

Re: K182093
Trade/Device Name: ZOLL ECG Analysis Software
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 20, 2018
Received: December 26, 2018

Dear Zachary Nelson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182093

Device Name
ZOLL ECG Analysis Software

Indications for Use *(Describe)*
The ZOLL ECG Analysis Software is intended for use by qualified medical professionals for the assessment of arrhythmias. The ECG Analysis Software supports reading and analysis of ECG data recorded in compatible formats. The ECG Analysis Software is intended for use with ECG management software through an electronic interface. The ECG Analysis Software provides ECG signal processing and analysis on a beat by beat basis, QRS and Ectopic Beat detection, heart rate measurement, and rhythm analysis. The ECG Analysis Software is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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7. 510(k) Summary

510(k) Owner:	**ZOLL Manufacturing Corporation** **121 Gamma Drive** **Pittsburgh, PA 51238** **U. S. A.**
Contact:	**Zachary Nelson** **Sr. Regulatory Affairs Engineer** **Phone: 412-968-3333 x14814** **Fax: 412-592-0953** **Email: znelson@zoll.com**
Date Summary Prepared:	**January 24, 2019**
Trade Name:	**ZOLL ECG Analysis Software**
Common Name:	**ECG Analysis Software**
Device Classification Name:	**Electrocardiograph**
Product Code:	**DPS**
Classification Regulation:	**870.2340**
Device Classification:	**II**
Classification Panel:	**Cardiovascular (74)**
Predicate Device:	**Monebo Automated ECG Analysis and Interpretation Software Library (K062282)** *The predicate device has not been subjected to recall.*

Device Description

The ZOLL ECG Analysis Software is a SaMD (Software as a Medical Device) which is of Moderate Level of Concern. It is a software library consists of callable functions that are accessible through an Application Programming Interface (API).

The ZOLL ECG Analysis Software provides ECG signal processing, QRS detection, classification of normal/VEB/SVEB, heart rate measurement, and the following rhythm interpretation for up to 3 leads (any combination of the standard 12 leads) of captured ECG data:

- Bradycardia
- Tachycardia
- Atrial Fibrillation
- Pause
- Ventricular Runs
- Ventricular Bigeminy / Ventricular Trigeminy
- Ventricular Tachycardia
- Supraventricular Tachycardia
- 2nd Degree Atrioventricular (AV) Block
- 3rd Degree Atrioventricular (AV) Block

The ZOLL ECG Analysis Software is made up of:

- An ECG analysis engine that is responsible for ECG analysis and interpretation
- An API to access the ECG analysis engine

The functions of the ZOLL ECG Analysis Software are intended to be called by a Windows application program written in C++, C# or MATLAB using the Microsoft .NET architecture.

Furthermore, the ZOLL ECG Analysis Software requires the installation of MATLAB Runtime R2015B for execution. The ZOLL ECG Analysis Software has only been tested and validated to be used with MATLAB R2015B."

Indications for Use Statement

The ZOLL ECG Analysis Software is intended for use by qualified medical professionals for the assessment of arrhythmias. The ECG Analysis Software supports reading and analysis of ECG data recorded in compatible formats. The ECG Analysis Software is intended for use with ECG management software through an electronic interface. The ECG Analysis Software provides ECG signal processing and analysis on a beat by beat basis, QRS and Ectopic Beat detection, heart rate measurement, and rhythm analysis. The ECG Analysis Software is not intended for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

Level of Concern Statement

The ZOLL ECG Analysis Software is a Moderate Level of Concern Software Device.

The library is intended for use only with devices authorized for commercialization by FDA for acquiring an ECG signal.

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 treatment decision.

Technological Characteristics and Substantial Equivalence Discussion

The ZOLL ECG Analysis Software and the predicate device Monebo have the same intended use. Both of them are intended for ECG signal analysis and interpretation, intended for use with ECG management software, and not intended for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

The ZOLL ECG Analysis Software and Monebo have the same technological characteristics. Both of them are software libraries consist of callable functions that are accessible through an API. Both are provided to the users in compiled file (Dynamic Link Library) and for installation in the user's hardware. Both provide ECG signal processing, QRS detection, beat classification, heart rate measurement, and rhythm interpretation.

Table 7-1 provides further comparison between the ZOLL ECG Analysis Software and Monebo.

Table 7-1: Comparison Chart between the ZOLL ECG Analysis Software and Monebo

	ZOLL ECG Analysis Software (Subject Device)	**Monebo (Predicate Device)**	**Comparison**
Product Code	DPS	DPS	Same
Device Classification	Electrocardiograph	Electrocardiograph	Same
Regulation Number	870.2340	870.2340	Same
Device Class	II	II	Same
Intended Use	ECG signal analysis and interpretation	ECG signal analysis and interpretation	Same
Patient Population	Adult	Adult	Same
Level of Concern	Moderate	Moderate	Same

	ZOLL ECG Analysis Software (Subject Device)	**Monebo (Predicate Device)**	**Comparison**
Beat Classification	Classifies and label all beats as "N" (Normal), ("V") Ventricular Ectopic Beat, or ("A") Supraventricular Ectopic Beat.	Classifies and labels all beats as Normal (N) or Ventricular (V). V is a Ventricular Ectopic Beat.	Similar. Both the ZOLL ECG Analysis Software and Monebo classify and label Normal, VEB and SVEB. Monebo uses the term APC (Atrial Premature Contraction under their rhythm interpretation section), which is equivalent to SVEB. ZOLL ECG Analysis Software adopts the term SVEB following AAMI/ANSI EC 57:2012.
Measurement	Heart Rate	- Heart Rate - PR interval - QRS duration - QT interval	Similar. Both the ZOLL ECG Analysis Software and Monebo measure Heart Rate. Monebo additionally provides PR interval, QRS duration and QT interval, lacking of which does not affect the safety and effectiveness of the ZOLL ECG Analysis Software. Both the ZOLL ECG Analysis Software and Monebo are subjected to EC57 testing to verify the accuracy of Heart Rate measurement. Test results demonstrate that the ZOLL ECG Analysis Software is at least as safe and effective as Monebo.
Arrhythmia Detection	- Bradycardia - Tachycardia - Atrial Fibrillation - Pause - Ventricular Runs - Ventricular Bigeminy / Ventricular Trigeminy - Ventricular Tachycardia - Supraventricular Tachycardia - 2nd degree Atrioventricular (AV) Block - 3rd degree Atrioventricular (AV) Block	- *Normal Sinus Rhythm (NSR)* - Bradycardia - Tachycardia - Nodal Rhythm - Pause - *Premature Ventricular Complexes (PVC)* - *Atrial Premature Contraction (APC)* - Atrial Fibrillation or Flutter - Ventricular Tachycardia - Supraventricular Tachycardia - Ventricular Flutter - AV Blocks	Similar. Arrhythmia detected by the ZOLL ECG Analysis Software is a subset of Monebo. Those arrhythmia detected by Monebo but not by the ZOLL ECG Analysis Software are underlined, lacking of which does not affect the safety and effectiveness of the ZOLL ECG Analysis Software. Note that the ZOLL ECG Analysis Software does not explicitly label NSR, and that VEB and SVEB are equivalent to PVC and APC. ZOLL ECG Analysis Software adopts the term VEB and SVEB following AAMI/ANSI EC57:2102.

	ZOLL ECG Analysis Software (Subject Device)	Monebo (Predicate Device)	Comparison
		- Bundle Branch Block - Ventricular Trigeminy - Ventricular Bigeminy - Accelerated Idioventricular Rhythm	Both the ZOLL ECG Analysis Software and Monebo are subjected to EC57 testing to validate their arrhythmia detection capability. Test results demonstrate that the ZOLL ECG Analysis Software is at least as safe and effective as Monebo.

Verification and Validation Activities Data

Since the ZOLL ECG Analysis Software is a SaMD, safety and effectiveness for the software is demonstrated through verification and validation activities (V&V) at the unit, integration and system level. Validation includes performance testing following AAMI/ANSI EC 57:2012 Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms. **Table 7-2** below provides a summary of the V&V activities for the ZOLL ECG Analysis Software.

Table 7-2: Verification and Validation Activities**Title**	**Description**
Unit Tests	In this verification activity, the smallest testable parts of the ZOLL ECG Analysis Software are individually and independently scrutinized for proper operation. The test cases simulate various operation conditions and error conditions of the ZOLL ECG Analysis Software. Each test case has an input test vector and an expected output. The actual output of each test case is compared to the expected output. All unit tests pass.
Functional Tests	Also a part of the verification activities, functional tests are conducted at the integration level. This testing verifies that each function of the ZOLL ECG Analysis Software operates in conformance with the requirement specification when program units are combined. Similar to the unit tests, each functional test case simulates the operation conditions and boundary conditions of the ZOLL ECG Analysis Software. Each test case has an input test vector and an expected output. The actual output of each test case is compared to the expected output. All functional tests pass.
API Test	As the sole function of the API is to correctly transfer the input and output parameters into and out of the ZOLL ECG Analysis Software, the API Test therefore is a simple atomic test to verify that the API transfers the input and output parameters correctly. Test result demonstrates that the API correctly transfer the input and output parameters.
Performance Test	Performance test is the validation activity conducted for the ZOLL ECG Analysis Software. It is a system level testing that demonstrates the detection capability of the software. Following AAMI/ANSI EC 57:2012 Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms, the ZOLL ECG Analysis Software is applied to the ECG databases required by the standard. The ZOLL ECG Analysis Software is required to generate an attribute file with the analysis results. The test results from the ZOLL ECG Analysis Software are compared to the reference results (which are available as part of the databases) using the comparison applications. Results from the EC 57 testing demonstrates that the performance of the ZOLL ECG Analysis Software meets the clinical requirements for arrhythmia detection and heart rate estimation.

Conclusion

As demonstrated in this 510(k), the ZOLL ECG Analysis Software has the same intended use and technological characteristics as the predicate device Monebo. Both devices have the same questions of safety and effectiveness. Verification and validation activities demonstrate that the ZOLL ECG Analysis Software is at least as safe and effective as Monebo. Therefore, the ZOLL ECG Analysis Software is substantially equivalent to Monebo.