ZOLL Medical Corporation
Pooja Dalvi
Regulatory Affairs Specialist
269 & 271 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K180482
Trade/Device Name: ZOLL Propaq M
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DRT, DXN, DSK, CCK, DQA, DPS, FLL
Dated: February 22, 2018
Received: February 23, 2018

Dear Pooja Dalvi:

This letter corrects our substantially equivalent letter of November 30, 2018.

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Goodsell -S

Digitally signed by Nicole M. Goodsell -S
Date: 2019.05.31 11:27:32 -04'00'

For Matthew Hillebrenner
Acting Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K180482

Device Name
Propaq M

Indications for Use *(Describe)*

Electrocardiogram (ECG) Monitoring
The Propaq M system is indicated to monitor and/or record 3-, 5-, or 12-lead electrocardiogram (ECG) waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. ECG monitoring is indicated for patients from newborn (neonate) to adult, with and without heart dysfunction.

Non-Invasive Blood Pressure Monitoring
The Propaq M system is indicated for use to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. The non-invasive blood pressure monitoring feature is indicated for patients from newborn (neonate) to adult.

Temperature Monitoring
The Propaq M system is indicated for use to make continuous temperature measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The temperature monitoring feature is indicated for use in patients from newborn (neonate) to adult.

SpO2 Monitoring
The Propaq M system is indicated for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and/or carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin (SpHb), oxygen content (SpOC), pleth variability index (PVI), and perfusion index (PI) via the pulse Co-oximeter and accessories. The pulse Co-oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Propaq M Indications for Use (Form 3881) Cont.

510(k) number (if known): **K180482**

Device Name: **Propaq M**
Indications for Use (Cont.)

Respiration Monitoring
The Propaq M system is indicated for use to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. Because the measurement method actually measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It is not intended to be used as an apnea monitor. The respiration monitoring feature is indicated for use on patients from newborn (neonate) to adult.

CO2 Monitoring
The Propaq M system is indicated for use in continuous noninvasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and breath rate. The CO2 monitoring feature is indicated for use on patients from newborn (neonate) to adult.

Invasive Pressure Monitoring
The Propaq M system is indicated for use to display and make continuous invasive pressure measurements via a compatible pressure transducer. The invasive pressure monitoring feature is indicated for use on patients from newborn (neonate) to adult.

12-Lead Analysis
The Propaq M system is indicated for use in acquiring, analyzing and reporting physiological data via 12-lead ECG Analysis, and to provide interpretation of the data for consideration by caregivers. The 12-lead ECG Analysis feature is indicated for use on adults (> 18 years of age).

Web Console
The Propaq M system is indicated for the remote display of physiological data displayed on connected Propaq M systems via the Web Console feature, including electrocardiogram (ECG), non-invasive blood pressure (NIBP), temperature, and heart rate.

Mobile Streaming
The Propaq M Mobile Streaming Client Application is intended for use by trained medical personnel familiar with basic monitoring, vital sign assessment, and emergency cardiac care in order to remotely view near real-time patient and device data transmitted from connected Propaq M devices. It requires a clinician at the patient's side next to the Propaq M device. The information streamed to the client application helps the remote clinician make decisions on patient care supplemental to the clinician on site with the patient. **Important**: The remote clinician should not use Mobile Streaming as a primary diagnostic device, but instead use the data to consult with the clinician at the patient side.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ZOLL Medical Corporation
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978-421-9655
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510(k) Summary

Sponsor Information:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person: Pooja Dalvi
Regulatory Affairs Specialist
Phone: (978) 805-6293
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Email: pdalvi@zoll.com

Date of Summary: October 10, 2018

Device Name and Classification:

Device Name: ZOLL Propaq M

Common Name: Portable Patient Monitor

Classification Name: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms) (21 CFR 870.1025)

Product Code: Arrhythmia detector and alarm (including ST-segment measurement and alarm) (MHX)
Cardiac Monitors – including Cardio tachometer and Rate Alarms (DRT)
Noninvasive Blood Pressure Measurement System (DXN)
Blood Pressure Computer (DSK)
Carbon Dioxide Gas Analyzer (CCK)
Oximeter (DQA)
Electrocardiograph (DPS)
Clinical electronic thermometer (FLL)

Predicate Device: ZOLL Propaq XM (K121367)

Device Description

The proposed Propaq M is a portable monitor designed for use by trained medical personnel who are familiar with basic monitoring and vital signs assessment. In the currently cleared configuration, the Propaq M provides monitoring capabilities for ECG, Pulse CO-Oximetry (SpO2), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), End Tidal CO_2, Temperature, and Respiration. The device is powered by an auxiliary power supply or an easily replaced battery pack that is quickly recharged in the device when it is connected to the auxiliary power supply.

With the current application, we propose a revision to the Propaq M device software to introduce Mobile Streaming Client (MSC) Software Application. The proposed MSC Application is a software application used in adjunct to the Propaq M device. It is intended for use by trained medical personnel familiar with basic monitoring, vital sign assessment, and emergency cardiac care in order to remotely view patient and device data transmitted from a connected Propaq M device.

Use of MSC requires a clinician at the patient's side next to the Propaq M device. The information streamed to the client application helps a remote clinician make decisions on patient care supplemental to the decisions made by the clinician on site with the patient. The MSC Application is a software application separate from the Propaq M device and its software. The remote clinician(s) utilize the client application from a desktop computer that allows them to remotely view the streamed data in real-time from active ZOLL Propaq M devices in the field. MSC is a server-based application viewed through a web browser via the MSC Website. With Mobile Streaming the remote user can:

- View the patient's top two waveforms and up to eight physiological parameters received from a Propaq M device
- View device alarms and equipment alerts issued by the Propaq M device
- View Propaq M device status messages
- View patient demographic data
- View, print, and save reports

The remote clinician should not use Mobile Streaming as a primary diagnostic device, but instead use the data to consult with the clinician at the patient side. The remote users cannot make any changes on, or control any aspects of, the Propaq M device using the MSC application.

Indications for Use

Electrocardiogram (ECG) Monitoring
The Propaq M system is indicated to monitor and/or record 3-, 5-, or 12-lead electrocardiogram (ECG) waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. ECG monitoring is indicated for patients from newborn (neonate) to adult, with and without heart dysfunction.

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The Propaq M Mobile Streaming Client Application is intended for use by trained medical personnel familiar with basic monitoring, vital sign assessment, and emergency cardiac care in order to remotely view near real-time patient and device data transmitted from connected Propaq M devices. It requires a clinician at the patient's side next to the Propaq M device. The information streamed to the client application helps the remote clinician make decisions on patient care supplemental to the clinician on site with the patient. **Important**: The remote clinician should not use Mobile Streaming as a primary diagnostic device, but instead use the data to consult with the clinician at the patient side.

Comparison of Technological Characteristics:

The proposed Propaq M device (also referred as Propaq XM) is an alternate configuration of the ZOLL X Series device (reviewed and approved by the agency under P160022) that depopulates the defibrillator/pacer module, as Propaq M is a monitoring device only. Both devices, Propaq M and X Series, are based on the same software architecture. Therefore, all the features supported by the X Series device, with the exception of the defibrillation, CPR monitoring and pacing features, can be supported by the Propaq M device.

Features/Functionalities	Propaq XM (K121367)	Proposed Propaq M	Substantial Equivalence
ECG Monitoring	✓	✓	Same
CO_2 Monitoring	✓	✓	Same
SpO_2, SpCO and SpMet Monitoring	✓	✓	Same
SpHb, SpOC, PVI and PI Monitoring	N/A	✓	Same
Respiration Monitoring	✓	✓	Same
Impedance Pneumography	✓	✓	Same
Invasive Blood Pressure Monitoring	✓	✓	Same
Non-Invasive Blood Pressure Monitoring	✓	✓	Same
Temperature Monitoring	✓	✓	Same
12-Lead ECG Interpretive Function	✓	✓	Same
Data Recording	✓	✓	Same
Communications	Wi-Fi, Bluetooth, USB cellular modem	Wi-Fi, Bluetooth, USB cellular modem and Ethernet Cable	Same The proposed Propaq M device additionally offers Ethernet communication option same as X Series.
Printer	Not offered	✓	Same
Web Console	Not offered	✓	Same

Features/Functionalities	Propaq XM (K121367)	Proposed Propaq M	Substantial Equivalence
Defibrillation	Not offered	Not offered	Proposed Propaq M is a Monitoring Device only and thus does not support defibrillation, CPR monitoring and pacing functionalities.
CPR Monitoring	Not offered	Not offered	
External Transcutaneous Pacing	Not offered	Not offered	

With the current application we are proposing to introduce the Mobile Streaming Client (MSC) application which is a software application intended to be used in adjunct to the Propaq M device. Like the existing Web Console feature that was reviewed and cleared by the agency under 510(k) application K133484, the MSC application allows a clinician to view waveforms and physiological data streamed from the Propaq M device at a remote location while the Propaq M is connected to a network.

Both features, the MSC and the Web Console, are capable of displaying physiological patient data that can be accessed by authorized users through a web browser technology. The Web Console and MSC Application displays same patient medical data and vital information that is captured from the device. Utilizing both the features does not affect or control the monitoring capabilities of the connected device in any way. No new issues of safety or effectiveness are raised by this premarket notification.

Substantial Equivalence – Non-Clinical Evidence:

The following performance data were provided in support of substantial equivalence determination:

Software Verification and Validation

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 Submission for Software Contained Medical Devices". The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could result in serious injury or death to the patient.
Extensive performance testing in the form of the software verification and system level validation ensured that the Propaq M performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications.

Safety testing per the international recognized standards

The device was evaluated and found to be in compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-2-25, ISO 80601-2-61and other applicable particular standards.
Safety testing ensures that the device complies with applicable sections of recognized industry and safety standards.

Electrical Safety and electromagnetic compatibility (EMC)

With the current submission, we are proposing to revise the Propaq M device software to introduce Mobile Streaming Client (MSC) Software Application. As the proposed modification involves a software-only change, the Electromagnetic Compatibility and Electrical Safety aspect of the Propaq M device has not been impacted by the proposed change.

Usability Testing

Usability evaluation was conducted to determine the appropriate usability activities for the Propaq M Mobile Streaming Client Application. As part of this process the primary operating functions, intended users and use scenarios and corresponding use related hazards were assessed.

Substantial Equivalence –Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence.

Conclusion:

The information provided in this 510(k) demonstrates that the proposed Propaq M device is substantially equivalent to indicated commercially distributed devices with regard to performance, safety and effectiveness.