March 9, 2021

ZOLL Medical Corporation
Elizabeth McMeniman
Director, Regulatory Affairs
269 Mill Road
Chelmsford, Massachusetts 01824

Re: K202375/S002
Trade/Device Name: ZOLL Propaq M
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II
Product Code: MWI, DRT, DXN, DSK, CCK, DQA, DPS, FLL
Dated: August 19, 2020
Received: August 20, 2020

Dear Elizabeth McMeniman:

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,

Jennifer Shih Kozen
Assistant 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)*

K202375

Device Name
ZOLL® 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.

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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)*

K202375

Device Name
ZOLL® Propaq® M

Indications for Use *(Describe)*

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.

TBI Dashboard

The Propaq M system is indicated to provide graphical trend data for SpO2, Systolic BP (SBP) and EtCO2 as well as ventilation assistance relevant to the management of a TBI patient.

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)

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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)*
K202375

Device Name
ZOLL® Propaq® M

Indications for Use *(Describe)*

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.

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)

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510(k) Summary

Sponsor Information:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person: Elizabeth McMeniman
Director, Regulatory Affairs
Phone: (978) 569-6862
Fax: (978) 421-0010
Email: emcmeniman@zoll.com

Date of Summary: September 1, 2020

Device Name and Classification:

Device Name: ZOLL® Propaq® M
Common Name: Portable Patient Monitor
Regulatory Class: Class II
Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) (21 CFR 870.2300)

Product Code: Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms) (MWI)
Cardiac Monitors – including Cardiotachometer 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 Devices:

Trade Name: ZOLL® Propaq® M
Regulation Number: 21 CFR 870.2300
Regulatory Class: Class II
Product Code: MWI, DRT, DXN, DSK, CCK, DQA, DPS, FLL
Identification Predicate Device: ZOLL® Propaq® M, K180482

Trade Name: ZOLL® X Series®
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX, LDD, DRT, DRO, DXN, DSK, CCK, DQA
Identification Predicate Device: ZOLL® X Series®, K141774 (K141774 introduced the TBI Dashboard)

Device Description

The proposed ZOLL® 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 ZOLL® Propaq® M provides monitoring capabilities for ECG, Pulse CO-Oximetry (SpO_2), 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.

The product is designed for use in hospital, EMS, and rugged military environments. The unit has a large colorful LCD display of numerics and waveform data that provides easy visibility from across the room and at any angle. ECG, plethysmograph, and respiration waveform traces can be displayed simultaneously, providing easy access to all patient monitoring data at once. The display screen is configurable to allow the best visual layout according to monitoring needs.

The Propaq® M has a patient data review and collection system that allows the user to view, store, and transfer patient data. The Propaq® M unit contains a USB port, which the user can use to transfer data to a PC and, optionally, a printer, which can be used to print patient data.

The Propaq® M unit can send data through a wireless connection to remote locations. The unit can send 12-lead report snapshots (including trend data) or disclosure logs to a recipient via a ZOLL® server. In addition, full disclosure cases, which also contain trend data, can be automatically retrieved from the Propaq® M unit using ZOLL® RescueNet® or ePCR software.

Propaq® M models use an easily replaced rechargeable lithium-ion battery pack (the SurePower II Battery Pack). A new, fully charged battery pack typically delivers more than 8 hours of ECG monitoring. Use of other functions (such as higher screen brightness or shorter NIBP intervals) reduces this time

A clinical dashboard for monitoring patients with suspected traumatic brain injury (TBI) has been added as part of Software Version 02.34 of the proposed Propaq® M device. The TBI Dashboard was initially cleared for ZOLL® X Series® (K141774) to be displayed on a separate mobile device that connects to the main device (ZOLL® X Series®) via Bluetooth. The proposed feature is to display the TBI Dashboard directly on the Propaq® M device via Software 02.34. The TBI Dashboard presents the user with graphical trend plots of 3 different parameters – (1) 15 minutes of systolic blood pressure (SBP), (2) 3

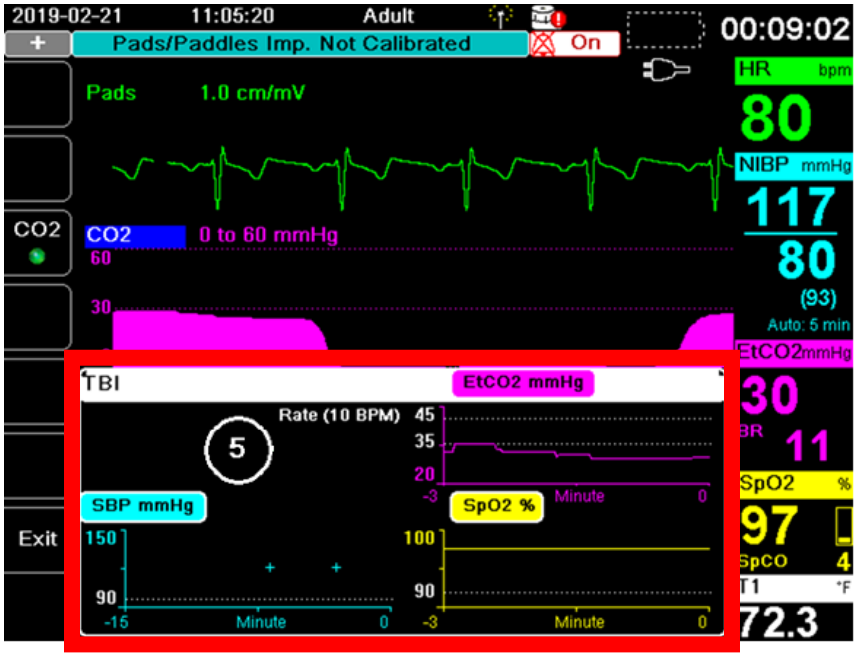
minutes of oxygen saturation of arterial hemoglobin (SpO_2), and (3) 3 minutes of carbon dioxide concentration of the expired breath ($EtCO_2$). The proposed ZOLL® Propaq® M device already provides this information in tabular format and in the live parameter boxes. The TBI Dashboard groups the information on one screen in a graphical format. The trend graphs display supervisor-configurable limits to allow the user to monitor patient parameters based on their local protocols. These protocol limits only appear in Adult mode. There is also a ventilation panel available on the TBI Dashboard to assist the user with manual ventilations. The TBI Dashboard allows the user to modify the target ventilation rate, the scale of each graphical trend, and to turn the ventilation timer and prompt on or off.

The Indications for use section in the Propaq® M Operator's Guide was updated to include the following statement for introducing of the TBI Dashboard:

TBI Dashboard
The Propaq® M system is indicated to provide graphical trend data for SpO_2, Systolic BP (SBP) and $EtCO_2$ as well as ventilation assistance relevant to the management of a TBI patient.

The lower half of **Figure 1**, identified by the red box, depicts the TBI Dashboard on the host device's screen and includes the SBP (teal), SpO_2 (yellow), and $EtCO_2$ (purple) trend graphs.

Figure 1: TBI Dashboard displayed on front panel user interface



Software Version 02.34 introduces automatic retries of failed 12-Lead report transmissions. While legacy Software of the Propaq® M attempts transmission of the 12-Lead report only once, the new proposed Software Version 02.34 attempts re-transmission up to five times if the initial attempt fails. This feature is a non-clinical enhancement since it affects only an external communication feature of the device with no impact to the acquiring, analyzing, or reporting process of ECG data.

The Propaq® M device is an alternate configuration of the ZOLL® X Series® device that depopulates the defibrillator/pacer module circuitry. Removal of this circuitry also removes CPR Monitoring capability from the device as the sensor that enables the CPR feature resides in the defibrillation electrodes. Physical

changes to the proposed Propaq® M device are limited to removing the defibrillator and pacer modules, removing the defibrillator and pacer controls from the front keypad, and changing the color scheme of the device. The remaining features and functions of the proposed Propaq® M device are identical to the existing ZOLL® X Series® model. In order to simulate the functioning of the Propaq® M device, a regression testing was conducted on the X Series device by disabling the defibrillator/pacer module, which ensures the effective functioning of the proposed Propaq® M device. The TBI Dashboard was introduced and cleared for the ZOLL® X Series® (K141774) to be displayed on a separate mobile device that connects to the main device (ZOLL® X Series®) via Bluetooth. The new Software Version 02.34 (TBI Dashboard installed on device) was introduced to ZOLL® X Series® and submitted to the agency under P160022/S013 on August 28, 2019.

The ZOLL® Propaq® M is a depopulated configuration of the ZOLL® X Series® device. The defibrillator/pacer module (circuit boards) in the Propaq® M software configuration is removed as Propaq® M is a monitoring device. The TBI Dashboard was introduced and cleared for the ZOLL® X Series® (K141774) to be displayed on a separate mobile device that connects to the main device via Bluetooth. The new Software Version 02.34 (TBI Dashboard installed on device) was introduced to ZOLL® X Series® and submitted to the agency under P160022/S013 on August 28, 2019.

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.

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.

SpO_2 Monitoring
The Propaq® M system is indicated for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), 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.

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.

CO_2 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 CO_2 monitoring feature is indicated for use on patients from newborn (neonate) to adult.

TBI Dashboard
The Propaq® M system is indicated to provide graphical trend data for SpO_2, Systolic BP (SBP) and $EtCO_2$ as well as ventilation assistance relevant to the management of a TBI patient.

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.

Comparison of Technological Characteristics:

The principles of operation are identical between the predicate ZOLL® Propaq® M (K180482) and subject device ZOLL® Propaq® M. The subject device is an easy-to-use portable monitor that has the following monitoring capabilities: ECG, CO-Oximeter, Non-invasive Blood Pressure, IBP, CO_2, SpO_2, Temperature, and Respiration. The technological difference between the ZOLL® Propaq® M subject device and the predicate device ZOLL® Propaq® M (K180482) is the introduction of Software 02.34/ TBI Dashboard. Therefore, the ZOLL® X Series® (K141774) will be referenced as a predicate for the TBI Dashboard.

Substantial Equivalence – Non-Clinical Evidence:

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

Software Verification and Validation

The Propaq® M device is an alternate configuration of the ZOLL® X Series® device that depopulates the defibrillator/pacer module circuitry. Removal of this circuitry also removes CPR Monitoring capability from the device as the sensor that enables the CPR feature resides in the defibrillation electrodes. Physical changes to the proposed Propaq® M device are limited to removing the defibrillator and pacer modules, removing the defibrillator and pacer controls from the front keypad, and changing the color scheme of the device. The remaining features and functions of the proposed Propaq® M device are identical to the existing ZOLL® X Series® model. In order to simulate the functioning of the Propaq® M device, a regression testing

was conducted on the X Series device by disabling the defibrillator/pacer module, which ensures the effective functioning of the proposed Propaq® M device.

As X Series® encompasses a larger set of functionalities than the Propaq® M device, Software verification and validation testing were conducted for the ZOLL® X Series® (P160022) 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*". Thus, the verification and validation relevant to X Series® device is also applicable to proposed Propaq® M device.

Performance testing in the form of the software verification and system level validation for the ZOLL® X Series® (P160022) 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 the standards identified in **Table 1**.

Table 1: Propaq® M Standards

FDA Consensus #	Standard Designation
19-4	IEC 60601-1: 2005/A1:2012/COR 1 2014
19-8	IEC 60601-1-2: 2014
5-89	IEC 60601-1-6: 2013
5-76	IEC 60601-1-8:2006/A1:2012
3-105	IEC 60601-2-25: 2011
3-126	IEC 60601-2-27: 2011
3-115	IEC 60601-2-34: 2011
N/A	IEC 60601-2-49: 2011
13-79	IEC 62304: 2006 AMD 1: 2015
5-114	IEC 62366-1:2015 COR 1 2016
3-152	ISO 80601-2-30: 2009
N/A	ISO 80601-2-55: 2011/AC: 2012
N/A	ISO 80601-2-56: 2009
N/A	ISO 80601-2-61: 2011
2-220	EN ISO 10993-1: 2009 AC: 2010
5-117	EN ISO 15223-1: 2016 COR 2017
N/A	BS EN 1041: 2008+A1:2013
5-40	EN ISO 14971: 2012

Safety testing ensures that the device complies with applicable sections of recognized industry and safety standards. No new safety testing was conducted with the introduction of the changes proposed in this application.

Electrical Safety and electromagnetic compatibility (EMC)

At this time ZOLL® proposes to revise the Propaq® M device software to introduce TBI Dashboard and 12-Lead re-transmission. 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

Summative usability evaluations were performed for the ZOLL® X Series® to validate the usability of the new Software revision 02.34 user interface. All identified use-related hazards have been found to be mitigated to acceptable levels.

The 12-Lead transmission retry enhancement does not change the user interface or the user interaction with the device. The process of capturing a 12-Lead, selecting the 12-Lead to send, selecting the transmission destination and sending the file will remain the same. If the transmission fails due to a connection issue, the device will attempt to automatically re-try the transmission up to 5 times. After 5 retries the user would revert to the previous method of manually transmitting the file. Previously, the user would need to manually transmit the case file upon each transmission failure. Therefore, usability testing is not required for the 12-Lead transmission feature.

Substantial Equivalence – Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence. However, relevant clinical literature is provided in Section 20. Performance Testing – Clinical.

Conclusion:

The information provided in this 510(k) demonstrates that the proposed Propaq® M is substantially equivalent to its predicate ZOLL® Propaq® (K180482) and ZOLL® X Series® (K141774) for TBI Dashboard for the new introduced Software Release 02.34.