July 24, 2018

Philips Medical Systems
Theresa Poole
Regulatory Specialist
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K180017
Trade/Device Name: MX40 Release C.01
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, DQA, DRW, DSA, MSX, DRG, DRT, DSI, MLD
Dated: June 25, 2018
Received: June 27, 2018

Dear Theresa Poole:

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,

Deborah Castillo

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180017

Device Name
Philips MX40 Release C.01

Indications for Use *(Describe)*

The intended use of the MX40 is to:
The device is intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.
Indications for Use
Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals.

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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510(k) Summary
MX40 Release C.01

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92(c).

Date Prepared: 29 December 2017

I. Submitter's name and address

Manufacturer: Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810 USA

Contact Person: Theresa Poole
Regulatory Affairs Specialist
Philips Medical Systems
3000 Minuteman Road, MS0480
Andover, MA 01810-1099

Tel: 978 659 7621
Fax: 978 685 5624
Email: theresa.poole@philips.com

II. Device information

Device Name: MX40 Release C.01
Common Name: Physiological Monitor, Patient Monitor
Classification panel: 74 - Cardiovascular

Classification names are as follows:

Classification	ProCode	Description
§870.1025, II	DSI	Detector and alarm, arrhythmia
§870.1025, II	MLD	Monitor, ST Segment with Alarm
§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
§870.2700, II	DQA	Oximeter
§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
§870.2300, II	MSX	System, Network and Communication, Physiological Monitors
§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
§870.2300, II	DRT	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)

III. Predicate device information

Trade name: INTELLIVUE MX40 PATIENT MONITOR
Manufacturer: Philips Medical Systems
510(k) clearance: K172226
Classification name: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)

Device class:	Class II
Classification regulation:	21 CFR 870.1025
Classification panel:	Cardiovascular
Product code:	MHX

IV. Device Description

The MX40 is a multi-parameter, battery operated patient monitor that is small enough to be worn by the patient. Its multi-radio design enables device operation within existing Philips telemetry networks while providing compatibility to the IntelliVue Information Center solutions. Along with infrastructure radios, the MX40 integrates a short-range radio (SRR), enabling wireless connectivity to the IntelliVue family of monitors. Acquired physiological data, along with physiological alarms and technical alert information are provided to multiple monitoring systems (local, bedsides and /or information systems).

Previously cleared compatible Accessories are still in use, compatibility to additional Massimo accessories are documented in this filing. The MX40 is compatible with the legally marketed Philips CL SpO2 Pod and CL NBP Pod (K101600, K111905). The CL SpO2/NBP Pods are small battery powered devices that measure oxygen saturation, pulse rate and blood pressure, pulse rate, respectively. A list of all accessories is available in the Instructions for Use.

V. Intended use/ Indications for Use

MX40 Intended Use/Indications for Use	The intended use of the MX40 is to: The device is intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals. Indications for Use Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals. Rx only.

Comparison of Technological Characteristics with the Predicate Device

The device has the same technological characteristics as the legally marketed predicate devices. The change summary includes items listed in the table starting on page 4.

510(k) Summary K180017

Key Characteristic	Predicate K172226 (9 November 2017) Philips IntelliVue MX40 Release B.07	MX40 Release C.01
Indications for Use Intended Use Statement	Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals. Intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.	Same
Target Patient Population	Adult and pediatric	Same
Users	Trained health care professionals	Same
System Interface	Connects to the Philips IntelliVue Information Center for transmission of patient parameters	Same
Care and Cleaning	Available instructions in IFU	Same
Communication	Smart Hopping 1.4GHz (CTS) Radio 802.11a/b/g/h Radio Short Range Radio 2.4 GHz	Same
Multi-Parameter patient monitoring	ECG, Resp, SpO2, and NIBP (data acquisition for NIBP is not done by the MX40)	Same
Device Software, Device safety, environmental specifications, and all specifications of	Unchanged, as previously submitted	Masimo SET SpO2 measurement technology

measurement characteristics		
Device Accessories	Unchanged, as previously submitted	Masimo SET SpO2 Accessory compatibility added
Device Hardware	Unchanged, as previously submitted	Same
Charging method	Unchanged, as previously submitted	Same

Summary of Non-clinical testing

No performance standards have been issued under the authority of Section 514. The MX40 Release C.01 was tested in accordance with Philips verification and validation processes. Quality Assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validations

Summary of Clinical Testing

Clinical Performance testing for MX40 Release C.01 was not performed, as there were no new clinical applications that had hazards or risk mitigations that required a clinical performance testing to support equivalence.

Conclusions drawn from the Non-clinical and Clinical testing

Verification, validation, and testing activities, where required to establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate are performed. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The MX40 Release B.07 meets all defined reliability requirements and performance claims.

VI.Conclusion

In summary, there is no change in either intended use or in the fundamental scientific technology employed by the MX40 patient monitor in the modification for C.01. We consider these device modifications to be substantially equivalent to previously cleared devices. Additionally, substantial equivalence was demonstrated with non-clinical performance testing, which complied with the requirements specified in the international and FDA-recognized consensus standards. The non-clinical performance tests provided in this 510(k) premarket notification demonstrate that the subject device is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.