



November 9, 2017

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

Re: K172226

Trade/Device Name: MX40 Release B.07

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, DSI, DQA, DSA, DRW, DRG, MLD, MSX

Dated: July 18, 2017

Received: July 25, 2017

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. 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.

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.

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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

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)

K172226

Device Name

MX40 Release B.07

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

510(k) Summary MX40 Release B.07

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

Date Prepared: 17 July 2017

I. Submitter's name and address

Manufacturer: Philips Medical Systems
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II. Device information

Device Name: MX40 Release B.07
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

510(k) Summary

Trade name: INTELLIVUE MX40 PATIENT MONITOR
Manufacturer: Philips Medical Systems
510(k) clearance: K103646
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, bedside and /or information systems).

Previously cleared compatible Accessories are still in use, no new accessories 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.

510(k) Summary

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

Key Characteristic	Predicate MX40 K103646, K113125	MX40 Release B.07
Indications for Use Intended Use Statement	<p>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.</p> <p>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.</p>	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

510(k) Summary

<p>Device Software, Device safety, environmental specifications, and all specifications of measurement characteristics</p>	<p>Unchanged, as previously submitted</p>	<ol style="list-style-type: none"> 1. Heart Rate Alarm from Pulse, requires PIC iX version C.01 or higher. 2. Auto report battery inop (Technical Alert) when Standby is in low battery state 3. Support CI (Connection Indication) message transport using Unicast protocol for WLAN 4. Malfunc Inop for software license failure – Added self-test to MX40 to allow for confirmation of Software License version to assist users to identify compatibility to other systems 5. Claim IEC60601-1 3rd edition update IFU and Product Labeling appropriately 6. AAMI screen - A new portrait screen 1-wave and 2 numerics to support AAMI EC13 display, local control only & cannot default to this screen from PIC-iX
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510(k) Summary

Device Accessories	Unchanged, as previously submitted	MCS PigTail and Block Adapter* Hardware to support Respiration measurements. *Use of Block Adapter requires MX40 software B.06 or higher.
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 B.07 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 B.07 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 B.07. 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.