DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 7, 2017

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

Re: K163584
Trade/Device Name: M3290B Patient Information Center iX 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, DSI, MLD, DSH, MSX
Dated: June 8, 2017
Received: June 9, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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)*
K163584

Device Name
M3290B Patient Information Center iX Release C.01

Indications for Use *(Describe)*
The intended use of the Philips Patient Information Center iX software application is to:
Receive, aggregate, process, distribute and display physiologic waves, parameters, alarms and events at locations other than at the patient, for multiple patients.

Determine alarm conditions and generate alarm signals for Philips approved medical devices, that send physiological data and do not have the ability to determine the alarm condition.
- Algorithms present in the software are limited to the ST/AR ECG (for arrhythmia, ST Segment and QT Segment Monitoring) and SpO2.

Generate alarm signals for user notification, based on the alarm signal determined and sent by Philips approved medical devices.

Perform diagnostic 12-Lead analysis and interpretation based on raw ECG data samples provided from Philips approved medical devices. Result may be displayed, printed and/or distributed to Philips approved medical devices.

Provide review and trend application data, designed to contribute to the screening of patient condition All information or visual indications provided are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making, thus these applications are not intended for diagnoses or active patient monitoring where immediate action is required.

Provide connection to other systems not associated with active patient monitoring, such as information systems. The software performs the action to transfer, store, convert from one format to another according to preset specifications, or to display medical device data.

The Information Center Software is intended for use in professional healthcare facilities by trained healthcare professionals. The Information Center Software is not intended for home use.

Indicated for use when monitoring adult and/or specified pediatric subgroups (Newborn (neonate), Infant, Child, Adolescent) patients as indicated by labeling of the medical device providing the data.
Rx only.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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."*

# 510(k) Summary
# Patient Information Center iX Release C.01

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

Date Prepared: 5 July 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: M3290B Patient Information Center iX software Revision C.01*
Common Name: Central Station
Classification panel: Cardiovascular

Classification names are as follows:

| Classification | ProCode | Description |
|---|---|---|
| 870.1025, II | MHX | Physiological Monitor, Patient Monitor |
| 870.1025, II | DSI | Arrhythmia Detector and Alarm |
| 870.1025, II | MLD | Monitor, ST Alarm |
| 870.2800, II | DSH | Recorder, Magnetic Tape, Medical |
| 870.2300, II | MSX | System, Network and Communication, Physiological Monitors |

* In Release C.01 the name of the product will be changed from M3290B Philips IntelliVue Information Center iX (PIIC iX) to M3290B Patient Information Center (PIC iX), dropping the Philips and IntelliVue branding in the name. The M3290B model number does not change.

## III. Predicate device information

Trade name: M3290B Philips IntelliVue Information Center iX software Revision C.0
Manufacturer: Philips Medical Systems
510(k) clearance: K153702

| | |
|---|---|
| Classification name | Central Station |
| Device class: | Class II |
| Classification regulation: | 21 CFR 892.2300 |
| Classification panel: | Cardiovascular |
| Product code: | MSX |

## IV. Device Description

The Philips Patient Information Center uses off-the-shelf Windows PCs and servers, combined with the Patient Information Center iX M3290B software Release C.01 to provide centralized display of physiologic waves, parameters, and trends, format data for strip chart recordings printed reports, and secondary annunciation of alarms from other networked medical devices. The M3290B Software provides for the retrospective review of alarms, physiologic waves and parameters from its database. Additionally, the M3290B Software provides primary annunciation of alarms and configuration and control access for networked telemetry monitors.

Compatible Accessories include: Mobile Caregiver – a medical device data system, viewing only, mobile application associated with the Enhanced Web Viewing feature cleared in the predicate. This is not a new mobile application, and it has no changes that introduce significant risks for the PIC iX C.01 release.

## V. Intended use/ Indications for Use

M3290B Intended Use/Indications for Use

The intended use of the Philips Patient Information Center iX software application is to:

- Receive, aggregate, process, distribute and display physiologic waves, parameters, alarms and events at locations other than at the patient, for multiple patients.
- Determine alarm conditions and generate alarm signals for Philips approved medical devices, that send physiological data and do not have the ability to determine the alarm condition.
    - Algorithms present in the software are limited to the ST/AR ECG (for arrhythmia, ST Segment and QT Segment Monitoring) and SpO2.
- Generate alarm signals for user notification, based on the alarm signal determined and sent by Philips approved medical devices.

- Perform diagnostic 12-Lead analysis and interpretation based on raw ECG data samples provided from Philips approved medical devices. Result may be displayed, printed and/or distributed to Philips approved medical devices.

- Provide review and trend application data, designed to contribute to the screening of patient condition All information or visual indications provided are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making, thus these applications are not intended for diagnoses or active patient monitoring where immediate action is required.

- Provide connection to other systems not associated with active patient monitoring, such as information systems. The software performs the action to transfer, store, convert from one format to another according to preset specifications, or to display medical device data.

The Information Center Software is intended for use in professional healthcare facilities by trained healthcare professionals. The Information Center Software is not intended for home use.

Indicated for use when monitoring adult and/or specified pediatric subgroups (Newborn (neonate), Infant, Child, Adolescent) patients as indicated by labeling of the medical device providing the data.

Rx only.

## VI.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 below.

| Key Characteristic | Predicate Device<br>PIIC iX C.0 (K153702) | Subject Device<br>PIC iX C.01 |
|---|---|---|
| Applications | **Display Setup**<br><br>**Manage Patient**<br><br>**Alarm Measurement and Device Control** | • The PIC iX release C.01, Changes to support Overviews with Enterprise Link; namely, paradigm shift away from primary and overview monitoring to the concept of principal and ancillary sectors.<br><br>• The Auto ADT feature can be configured to admit, discharge, and transfer a patient directly from the hospital information system (HIS) to the PIC iX.<br><br>• Release C.01 PIC iX supports IntelliVue X3 Multi-Measurement Modules that are connected to IPM Release M.0 monitors and, Pulse alarm for MX40 B.07 and later. |
| Domain-Specific Services | **Alarm Management**<br><br>**Patient & Equipment Management** | • With PIC iX Release C.01, the Alarm Advisor application provides feedback on recurring alarm limit violations for a specific measurement over a period of time, frequent alarm notifications can be configured<br>• The Patient Management application provides the clinical user with information and controls. |

| | | |
|---|---|---|
| | | • Each patient can be monitored by one or more devices namely IPM, Efficia, PWD, MX40, MRx defibrillator/monitor, and NIBP and $SpO_2$ sensors. |
| Outbound Data Services | **Web/Mobility**<br><br>**12 Lead**<br><br>**Data Warehouse** | • The Web Proxy in PIC iX Release C.01 enables IPM Release M.0 monitors to display retrospective data as shown with web applications.<br>• For 12-lead ECG Export, the user can enter the order number, order reason, requested by, operator, facility, department and comment (1-5) fields .<br>•<br>• With PIC iX Release C.01, the monitor can resend up to the last 10 seconds of wave data.<br>• PIC iX Release C.01, allows to send additional non-ECG waves and these are stored in the Data Warehouse. |
| Platform | **Windows 8.1 OS**<br>Windows Server 2012 R2<br>Hardware Specified in IFU | Windows 10 IoT<br>Windows Server 2012 R2<br>Hardware Specified in IFU |

## VII. Performance Data

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

### Summary of Non-clinical testing

No performance standards have been issued under the authority of Section 514. The M3290B Philips IntelliVue Information Center iX software 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 M3290B Philips IntelliVue Information Center iX software 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 M3290B Philips IntelliVue Information Center iX software Release C.01 meets all defined reliability requirements and performance claims.

## VIII. Conclusion

M3290B Philips IntelliVue Information Center iX software Release C.01 is substantially equivalent to the predicate device M3290B Philips IntelliVue Information Center iX software Release C.0 (K153702) in terms of design features, fundamental scientific technology, intended use, and safety and effectiveness. 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.