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

December 3, 2014

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

Re: K143057
Trade/Device Name: M3290B Philips Intellivue Information Center iX Software Release B.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, DSH, DSI, MLD, MSX, OUG
Dated: November 6, 2014
Received: November 7, 2014

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 yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ODE Indications Statement

Indications for Use

510(k) Number (if known): _____

Device Name: ___M3290B IntelliVue Information Center iX Software Release B.01

Indications for Use:

Indicated for central monitoring of multiple adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Prescription Use ___Yes____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patient Monitoring
Quality & Regulatory Group
3000 Minuteman Road
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Andover, MA 01810
Tel: (978) 659-3000
Fax: (978) 685-5624

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

The submitter of this premarket notification is:

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This summary was prepared on 3 December 2014.

The name of this device is the M3290B Philips IntelliVue Information Center iX software Revision B.01
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
880.6310, I	OUG	Medical Device Data System

The M3290B Philips IntelliVue Information Center iX (PIIC iX) Release B.01 software is substantially equivalent to the previously cleared M3290B IntelliVue Information Center software, Release A.0 marketed pursuant to K102495.

The Philips IntelliVue Information Center iX Software Revision B.01 is central station software that runs on off-the-shelf Windows PCs and servers which can connect to recorders for waveform printing. It displays physiologic waves and parameters from multiple patient connected monitors and telemetry devices in summary or detailed format, and generates alarm signals. It provides retrospective review applications and a variety of data import and export functions.

The device has the same Indications for Use and Intended Use Statement as the legally marketed predicate devices.

The device has the same technological characteristics as the legally marketed predicate devices.

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 IntelliVue Information Center Software meets all defined reliability requirements and performance claims.