December 26, 2017

Philips Medizin Systeme Boeblingen GmbH
Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
Boeblingen, D-71034
GERMANY

Re: K172904
Trade/Device Name: IntelliVue Capnography Extension 867040, IntelliVue Microstream Extension 867041
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, BZQ, DXG, DRQ, FLL
Dated: October 25, 2017
Received: October 27, 2017

Dear Markus Stacha:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: K172904

Device Name: IntelliVue Capnography Extension 867040 and Microstream Extension 867041

Indications for Use *(Describe)*

Indications for Use statement for the Capnography Extension 867040:

The measurement extension adds physiological measurements (Mainstream / Sidestream CO2 and optionally temperature, invasive blood pressure, cardiac output) to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.
The measurement extension can only function when it is connected to a dedicated host device.

Indications for Use statement for the Microstream Extension 867041:

The measurement extension adds physiological measurements (Microstream CO2 and optionally temperature and invasive blood pressure) to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.
The measurement extension can only function when it is connected to a dedicated host device.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

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.

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510(k) Summary

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

1. Submitter of this premarket notification

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This summary was prepared on Dec 22, 2017.

2. The name and classification of the device

Trade name: IntelliVue Capnography Extension 867040 and Microstream Extension 867041
Common name: Multifunction Patient Monitor Module.

Primary regulation and classification: CFR Title 21 Part 868 – Anesthesiology Devices, Section 868.1400 'Carbon dioxide gas analyzer'. Device Class II. Product Code: CCK. Secondary Product Codes: BZQ, DXG, DRQ, DSA, FLL.

3. The new Philips IntelliVue Capnography Extension 867040 is substantially equivalent to the previously cleared Philips Capnography Extension M3014A marketed pursuant to K050762. The new Philips IntelliVue Microstream Extension 867041 is substantially equivalent to the previously cleared Philips Microstream Extension M3015B marketed pursuant to K993383 and K113441.

4. Description of the device

The new IntelliVue Capnography Extension 867040 and Microstream Extension 867041 are modifications of the legally marketed Philips Capnography Extension M3014A and Microstream Extension M3015B, respectively.

IntelliVue Capnography Extension 867040 and Microstream Extension 867041 are compact measuring devices without display and control elements that, in combination with dedicated host devices, add the following measurement parameters:

867040: Capnography (Mainstream / Sidestream CO2) and optionally temperature, invasive blood pressure, and cardiac output (C.O.)

867041: Microstream CO2 and optionally temperature and invasive blood pressure.

IntelliVue Capnography Extension 867040 and Microstream Extension 867041 use settings and power of the connected host device. Trend data and measurement settings from the measurements in the extensions are stored in the connected host device. The measurement extensions send processed waves, numerics and basic alerts to the host device.

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5. Intended Use

Indications for Use statement for the Capnography Extension 867040:

The measurement extension adds physiological measurements (Mainstream / Sidestream CO2 and optionally temperature, invasive blood pressure, cardiac output) to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.
The measurement extension can only function when it is connected to a dedicated host device.

Indications for Use statement for the Microstream Extension 867041:

The measurement extension adds physiological measurements (Microstream CO2 and optionally temperature and invasive blood pressure) to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.
The measurement extension can only function when it is connected to a dedicated host device.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

The Intended Use and Indications for Use for the new Capnography Extension 867040 are the same as those for the predicate Capnography Extension M3014A. The only difference is the Continuous Cardiac Output (CCO) measurement option. Whereas the predicate measurement extension M3014A supports CCO measurement together with the dedicated host device, the new measurement extension does not support this measurement.

The Intended Use and Indications for Use for the new Microstream Extension 867041 are the same as those for the predicate Microstream Extension M3015B.

6. Technological Characteristics

The new IntelliVue Capnography Extension 867040 and Microstream Extension 867041 have the same relevant technological characteristics as the predicates M3014A and M3015B with regard to energy sources, portability, and robustness.

Compared to the predicates M3014A and M3015B, in the new 867040 and 867041 several electronic components were replaced by state-of-the-art components and the form factor was adapted to fit the new housing. The former common PCA for invasive pressure and temperature measurements was divided into two PCAs.
The plastic materials of the housings of the predicates M3014A and M3015B have been changed in the new 867040 and 867041 from ABS and PC-FR to PBT and PC, in order to enhance mechanical and chemical resistance.
Biocompatibility aspects are not affected because the devices do not have contact with patients.

The fundamental scientific technology of the new IntelliVue Capnography Extension 867040 and Microstream Extension 867041 is the same as that of the predicates Capnography Extension M3014A and Microstream Extension M3015B.
The differences in technological characteristics between the new and the predicate devices do not raise different questions of safety or effectiveness.

7. Summary of V&V activities

The new IntelliVue Capnography Extension 867040 and Microstream Extension 867041 have been subject of a series of V&V activities:

- Compliance with relevant recognized consensus standards:
  - IEC 60601-1-2: 2007 (Ed. 3) (Electromagnetic Compatibility)
  - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1) (Basic safety and essential performance)
  - IEC 60601-2-34: 2011 (Ed. 3) (Invasive blood pressure monitoring equipment)
  - ISO 80601-2-55: 2011 (Ed. 1) (Respiratory gas monitors)
  - ISO 80601-2-56: 2009 (Ed. 1) (Clinical thermometers)
  - AAMI ANSI IEC 62304:2006 (Ed. 1) (Software life cycle processes)

  All applicable requirements have been met.
- Testing as required by the Hazard Analysis.

  All specified pass/fail criteria have been met. The test results have confirmed the effectiveness of the implemented design risk mitigation measures.
- Additional environmental testing (temperature, humidity) and mechanical testing (mechanical classes 7M1 and 7M3 and chemical resistance against disinfecting and cleaning agents)
  All specified test requirements have been met. The tests have confirmed that the new devices work according to their specifications and indicated claims during tests simulating general hospital conditions, handling and transport in hospital environments, disinfection, and storage.
- Performance bench testing of C.O. signal acquisition
  All specified test requirements have been met. The new devices perform according to the specified criteria that are the same as those for the predicate devices.
- Unit level tests, functional system level tests, and regression system level tests.
  The new devices perform according to the specified criteria. All specified test requirements have been met. The test results demonstrate that modified and previously available device functions work correctly according to the specifications and labeling claims.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new devices with respect to the predicates.
Testing comprised electrical and mechanical tests, EMC tests, environmental tests, performance tests, functional and regression tests.

Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.
The results demonstrate that the new devices meet all defined reliability requirements and performance claims.