PULSION Medical Systems SE  
% Mark Smith  
Manager, Regulatory Affairs  
Maquet Cardiovascular  
45 Barbour Pond Drive  
Wayne, New Jersey 07470  

Re: K172259  
Trade/Device Name: PulsioFlex Monitoring System  
Regulation Number: 21 CFR 870.1435  
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer  
Regulatory Class: Class II  
Product Code: DXG  
Dated: December 18, 2017  
Received: December 19, 2017  

Dear Mark Smith:

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](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/](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/)) and CDRH Learn ([http://www.fda.gov/Training/CDRHLearn](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](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,

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)
K172259

Device Name
PulsioFlex Monitoring System

Indications for Use (Describe)
The PulsioFlex Monitoring System is a diagnostic aid for the measurement and monitoring of blood pressure, cardiopulmonary, circulatory and organ function variables. The PulsioFlex Monitoring System is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. If a patient’s biometric data are entered, the PulsioFlex monitor presents the derived parameters indexed.

With the PiCCO Module cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. Both are used for the determination of other derived parameters.

With the CeVOX oximetry module connected to a compatible oximetry probe, the PulsioFlex Monitoring System measures continuous venous oxygen saturation to assess oxygen delivery and consumption.

The use of the PulsioFlex Monitoring System is indicated in patients where cardiovascular and organ monitoring is useful. This includes patients in surgical, medical, and other hospital units.

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
Prepared in accordance with 21 CFR Part 807.92

Date Prepared: January 18, 2018

Device Owner: PULSION Medical Systems SE
Hans-Riedl-Str. 17
85622 Feldkirchen
Germany

Contact Personnel: Mr. Mark Smith
Regulatory Affairs
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Phone: (585) 272-5274
Fax: (585) 272-5066

Device/System Name: PulsioFlex Monitoring System

Trade name(s): PulsioFlex Monitor
PiCCO Module  CeVOX Module

Device Generic Name: Single-function, pre-programmed diagnostic computer.

Classification: According to 21 CFR 870.1435 the device classification is Class II, Product code DXG.

Predicate Device: K122121, PulsioFlex Monitoring System with PiCCO Module
**Intended Use:** The PulsioFlex Monitoring System is a diagnostic aid for the measurement and monitoring of blood pressure, cardiopulmonary, circulatory and organ function variables. The PulsioFlex Monitoring System is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. If a patient's biometric data are entered, the PulsioFlex Monitor presents the derived parameters indexed.

- With the PiCCO Module cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. Both are used for the determination of other derived parameters.

- With the CeVOX oximetry module connected to a compatible oximetry probe, the PulsioFlex Monitoring System measures continuous venous oxygen saturation to assess oxygen delivery and consumption.

**Indications for Use:** The use of the PulsioFlex Monitoring System is indicated in patients where cardiovascular and organ monitoring is useful. This includes patients in surgical, medical, and other hospital units.

**Device Description:** The PulsioFlex Monitoring System is a patient monitoring system that consists of the following components:

a) PulsioFlex Monitor
b) CeVOX Optical Module
c) PiCCO Module

**Description of functionality:** The PulsioFlex Monitor receives incoming signals from the patient through the connections with the modules and the accessories applied to the patient. The measurement hardware in the
PulsioFlex Monitoring System provides the PulsioFlex host application (software) all data from the modules via USB protocol. The algorithms embedded in the monitor host application process the signals and provide parameter calculations. Based on the patient’s biometric data, the PulsioFlex Monitor presents the derived parameters indexed.

**Description of the components:**

a) The **PulsioFlex Monitor** displays various hemodynamic parameters depending on which module(s) is/are connected, i.e. the touch screen graphical user interface (GUI) is adaptable and automatically detects what modules are connected.

b) The **PulsioFlex Monitor with the PiCCO Module** provides the possibility to monitor cardiac output, both continuously (pulse contour analysis) and intermittently (thermodilution). A comprehensive list of parameters (absolute and indexed to patient biometric data) available while monitoring with the PulsioFlex Monitor connected to the PiCCO Module is shown below. The new parameters in this submission are marked **in bold and indicated with an asterisk (*)**.

### Thermodilution:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbr.</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Output, transpulmonary</td>
<td>CO</td>
<td>CI</td>
</tr>
<tr>
<td>Global End-Diastolic Volume</td>
<td>GEDV</td>
<td>GEDI</td>
</tr>
<tr>
<td>Extravascular Lung Water</td>
<td>EVLW</td>
<td>ELWI</td>
</tr>
<tr>
<td>Cardiac Function Index</td>
<td>CFI</td>
<td></td>
</tr>
<tr>
<td>*Global Ejection Fraction</td>
<td>GEF</td>
<td></td>
</tr>
<tr>
<td>*Pulmonary Vascular Permeability Index</td>
<td>PVPI</td>
<td></td>
</tr>
<tr>
<td>*Intrathoracic Blood Volume</td>
<td>ITBV</td>
<td>ITBI</td>
</tr>
</tbody>
</table>
Pulse Contour Analysis:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbr.</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Rate</td>
<td>HR</td>
<td></td>
</tr>
<tr>
<td>Mean Arterial Blood Pressure</td>
<td>MAP</td>
<td></td>
</tr>
<tr>
<td>Systolic Arterial Blood Pressure</td>
<td>APsys</td>
<td></td>
</tr>
<tr>
<td>Diastolic Arterial Blood Pressure</td>
<td>APdia</td>
<td></td>
</tr>
<tr>
<td>Continuous Cardiac Output</td>
<td>COₚₚ</td>
<td>CIₚₚ</td>
</tr>
<tr>
<td>Stroke Volume</td>
<td>SV</td>
<td>SVI</td>
</tr>
<tr>
<td>Systemic Vascular Resistance</td>
<td>SVR</td>
<td>SVRI</td>
</tr>
<tr>
<td>Stroke Volume Variation</td>
<td>SVV</td>
<td></td>
</tr>
<tr>
<td>Pulse Pressure Variation</td>
<td>PPV</td>
<td></td>
</tr>
<tr>
<td>*Cardiac Power Output</td>
<td>CPO</td>
<td>CPI</td>
</tr>
</tbody>
</table>

The PulsioFlex Monitor together with the CeVOX Optical Module continuously measures central venous oxygen saturation or mixed venous oxygen saturation depending on the position of the fibre optic oximetry probe. In combination with continuous cardiac output and by entering a value for arterial oxygen saturation and hemoglobin additional parameters can be calculated. Based on the patient’s biometric data, the PulsioFlex Monitor presents the derived parameters indexed. A comprehensive list of parameters available while monitoring with the PulsioFlex Monitor with the connected CeVOX Optical Module and a fibre optic oximetry probe are listed below. The new parameter in this submission is marked *in bold and indicated with an asterisk (*).*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Venous Oxygen Saturation</td>
<td>SᵥᵥO₂</td>
</tr>
<tr>
<td>Mixed Venous Oxygen Saturation</td>
<td>SᵥO₂</td>
</tr>
<tr>
<td>Oxygen Delivery</td>
<td>DO₂</td>
</tr>
<tr>
<td>Oxygen Delivery Index</td>
<td>DO₂ᵢ</td>
</tr>
<tr>
<td>Oxygen Consumption</td>
<td>VO₂</td>
</tr>
<tr>
<td>Oxygen Consumption Index</td>
<td>VO₂ᵢ</td>
</tr>
<tr>
<td>*Oxygen Extraction Ratio</td>
<td>O₂ER</td>
</tr>
</tbody>
</table>
Comparison to Predicate Device:
The PulsioFlex Monitoring System uses the same monitoring technology (COPC, CO and Oximetry), the same components (PulsioFlex Monitor, PiCCO Module and CeVOX Optical Module), the same measured parameters and the same default alarm limits as the predicate device PulsioFlex Monitoring System with PiCCO Module (K122121, cleared August 02, 2012).

Updates made to the PulsioFlex Monitoring System include:

- **Compliance to Electrical Safety Requirements**
  Minor hardware changes to the PulsioFlex Monitor and PiCCO Module in order to comply with the requirements in recognized electrical safety and electromagnetic compatibility standards.

- **New Graphical User Interface visualizations (GUI)**
  - **Organ View** – shows selected parameters visualized in relationship to the lung, heart and vessels.
  - **Spider View** – shows the continuous parameters dynamically.
  - **Profiles View** – shows the measured parameters in respect to their position to the normal or target value.
  - **Help Screens** – containing information about Setup, Parameter Info, Decision Model, Physio Overview, and General Information.
  - **Volume Test** – supports fluid management by tracking the parameters over a predefined time span when volume responsiveness test methods are in use.

- **HIPAA Compliance**
  PulsioFlex Monitoring System has included an option for the responsible organization to exclude patient information in printout and data recording to fulfil HIPAA requirements.

- **HL7**
  The data in the PulsioFlex Monitor can be transmitted via Ethernet to external Patient Data Management Systems (PDMS) using HL7 standard. HL7 for the PulsioFlex Monitoring System is limited to connecting and sending patient data to external Medical Systems.
- **New derived parameters**
  The additional derived parameters (GEF, CPO, PVPI, O₂ER, and ITBV) are calculated by the PulsioFlex Monitors host application (software) based on the previous cleared parameters in the predicate device PulsioFlex Monitoring System with PiCCO Module (K122121).

- **New Operating System**
  The subject device PulsioFlex Monitoring System is built on a Windows 7 Embedded Operating System whereas the predicate device PulsioFlex Monitoring System with PiCCO Module used a Windows XP Embedded Operating System.

**Performance Data:** The following verification activities were performed in support of a substantial equivalence determination.

**System Verification**
All hardware requirements were verified. Measurements of Cardiac Output parameters and Oximetry parameters were performed with the subject device. Individual modules were tested at a system level to verify safety and effectiveness.

**Electrical Safety and Electromagnetic Compatibility (EMC)**
The PulsioFlex Monitoring System is tested to be in compliance with the following standards: IEC 60601-1 (with US deviation according to AAMI/ANSI ES60601-1:2005/(R) 2012), IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 62304, IEC 62366, IEC 62366-1, IEC 60601-2-34, and IEC 60601-2-49.

**Software Verification**
The PulsioFlex Monitoring System’s software is considered a Moderate Level of Concern. Software verification was performed considering FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and according to the standard IEC 62304 “Medical device software - Software life-cycle processes”.
**Cybersecurity Information**
Threats and vulnerabilities have been assessed according FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”. Appropriate Methods of Control (MOC) were implemented and verified to reduce cybersecurity risks as far as possible. Throughout the lifecycle of the PulsioFlex Monitor, it is assured that the device maintains its safety and effectiveness.

**Usability Testing**
A Summative Usability Evaluation including new GUI visualizations and derived parameters was performed considering FDA’s Guidance for Industry and FDA Staff, “Applying Human Factors and Usability Engineering to Medical Devices” and according to the standard IEC 62366-1 “Medical devices – Part 1: Application of usability engineering to medical devices”. The PulsioFlex Monitoring System has been found to be safe and effective for the intended users, uses, and use environments.

**Non-Clinical Performance:**
Completion of all verification activities demonstrated that the subject device meets all design and performance requirements. Verification activities performed confirmed that the differences in the design did not adversely affect the safety and effectiveness of the subject device.

**Clinical Performance:**
Clinical data was not required for this device.

**Conclusion:**
The PulsioFlex Monitoring System is substantially equivalent to the legally marketed predicate PulsioFlex Monitoring System with PiCCO Module (K122121).