April 30, 2019

Pulsion Medical Systems SE
℅ Mark Smith
Manager, Regulatory Affairs
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K192169
Trade/Device Name: PulsioFlex Monitoring System with ProAQT Sensor
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: March 31, 2020
Received: April 1, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192169

Device Name
PulsioFlex Monitoring System with ProAQT Sensor

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.
- With the ProAQT Sensor, the PulsioFlex Monitoring System uses arterial pulse contour analysis for continuous hemodynamic monitoring.

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	August 06, 2019
Device Owner	PULSION Medical Systems SE Hans-Riedl-Str. 17 85622 Feldkirchen Germany
Contact Personnel	Mr. Mark Smith Regulatory Affairs
Email	mark.n.smith@getinge.com
Phone	(585) 272-5274
Fax	(585) 272-5066
System Name	PulsioFlex Monitoring System with ProAQT
Trade name(s)	PulsioFlex Monitor PiCCO Module CeVOX Module ProAQT Sensor
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	K172259, PulsioFlex Monitoring System

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.

- With the ProAQT Sensor, the PulsioFlex Monitoring System uses arterial pulse contour analysis for continuous hemodynamic monitoring.

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) PiCCO Module
c) CeVOX Optical Module
d) ProAQT Sensor

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.

Thermodilution

Parameter	Abbr.	Index
Cardiac Output, transpulmonary	tdCO	tdCI
Global End-Diastolic Volume	GEDV	GEDI
Extravascular Lung Water	EVLW	ELWI
Cardiac Function Index	CFI	
Global Ejection Fraction	GEF	
Pulmonary Vascular Permeability Index	PVPI	
Intrathoracic Blood Volume	ITBV	ITBI

Pulse Contour Analysis

Parameter	Abbr.	Index
Heart Rate	HR	
Mean Arterial Blood Pressure	MAP	
Central Venous Pressure	CVP	
Systolic Arterial Blood Pressure	APsys	
Diastolic Arterial Blood Pressure	APdia	
Pulse Contour Cardiac Output (*)	CO_{PC}	CI_{PC}
Stroke Volume	SV	SVI
Systemic Vascular Resistance	SVR	SVRI
Stroke Volume Variation	SVV	
Pulse Pressure Variation	PPV	
Cardiac Power Output	CPO	CPI

c) 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 fiber 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 fiber optic oximetry probe are listed below.

Parameter	Abbr.	Index
Central Venous Oxygen Saturation	$ScvO_2$	
Venous Oxygen Saturation	SvO_2	
Oxygen Delivery	DO_2	DO_2I
Oxygen Consumption	VO_2	VO_2I
Oxygen Extraction Ratio	O_2ER	

d) The **PulsioFlex Monitor with the ProAQT Sensor** determines the cardiac output by means of pulse contour analysis. The ProAQT Sensor is connected in series to a pre-installed blood pressure measurement system. The required blood pressure data is measured and transferred to the PulsioFlex Monitor that analyzes the data and calculates and displays the associated parameters. A comprehensive list of parameters (absolute and indexed to patient biometric data) available while monitoring with the PulsioFlex Monitor connected to the ProAQT Sensor is shown below.

Pulse Contour Analysis

Parameter	Abbr.	Index
Heart Rate	HR	
Mean Arterial Blood Pressure	MAP	
Central Venous Pressure	CVP	
Systolic Arterial Blood Pressure	APsys	
Diastolic Arterial Blood Pressure	APdia	
Pulse Contour Cardiac Output (*)	CO_{Cal}	CI_{Cal}
Stroke Volume	SV	SVI
Stroke Volume Variation	SVV	
Pulse Pressure Variation	PPV	
Cardiac Power Output	CPO	CPI

(*) Subscripts “cal” and “pc” are used to distinguish between different calibration methods for pulse contour analysis:
- “pc”: Calibration with CO from thermodilution
- “cal”: Calibration with CO from user input using an external measurement method

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Comparison to Predicate Device

The PulsioFlex Monitoring System with ProAQT Sensor uses the same monitoring technology, the same measured parameters and the same default alarm limits as the predicate device PulsioFlex Monitoring System (K172259).

Updates made to the PulsioFlex Monitoring System with ProAQT include:

- **Inclusion of the use of the ProAQT Sensor**

The use of the ProAQT Sensor allows the PulsioFlex Monitoring System to use only arterial pulse contour analysis for continuous hemodynamic monitoring.

- **PulsioFlex Monitor - Software**

The software was updated to V5.2 due to necessary adaptations related to the cardiac output calibration with the ProAQT Sensor. Specifically for the ProAQT Sensor, externally derived cardiac output (e.g. by doppler ultrasound technique) serves as calibration input. The arterial blood pressure signal from the ProAQT Sensor uses the identical algorithm as the PiCCO Technology.
Performance and compatibility of the ProAQT Sensor with the PulsioFlex Monitor has been successfully verified.

Performance Data

The following verification activities were performed in support of a substantial equivalence determination.

Performance Testing

Technical and functional requirements for the ProAQT Sensor have been verified within performance testing for the changes. The following verifications were conducted:

- Visual, dimensional and handling tests
- Lifetime test
- Verification of required product characteristics
- Tests according to ISO 594-1:1986 and ISO 594-2:1998 requirements
- Tests according to ANSI/AAMI BP22 requirements
- Tests according to ISO 11607-1 requirements

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".

Electrical Safety and Electromagnetic Compatibility (EMC)
The PulsioFlex Monitoring System with ProAQT 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.

Sterilization Validation
The sterility is assured by an EO (Ethylene Oxide) sterilization of the product within the unopened and undamaged packaging. Tests demonstrate that the sterilization process and equipment are capable of reliably and consistently sterilizing to a minimum Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated according to ISO 11135 requirements and revalidated according to the overkill / cycle calculation approach described in ISO 11135:2014. Residuals were evaluated by exhaustive extraction according to ISO 10993-7:2009.

Biocompatibility
The biocompatibility evaluation for the ProAQT Sensor was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The following toxicological endpoints are considered:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity / Irritation
- Acute Systemic Toxicity
- Material-mediated Pyrogenicity
- Subacute / Subchronic Toxicity
- Hemocompatibility

Shelf-Life Testing
Accelerated and real time aging was conducted to demonstrate 36 months (3 years) of shelf life. The study was conducted with increments of 18 and 36 months.
The results for both increments after accelerated aging, as well as after real time aging of 36 months, demonstrate that the ProAQT

Sensor fulfills this requirement. It is concluded that a shelf life of 36 months is verified by the available data.

Usability Testing
A Summative Usability Evaluation 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 with ProAQT Sensor 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 demonstrates that the pulse contour algorithm is able to process pressure signals from femoral, brachial, axillary and also radial artery adequately.
Conclusion	The PulsioFlex Monitoring System with ProAQT Sensor is substantially equivalent to the legally marketed predicate PulsioFlex Monitoring System (K172259).