February 21, 2018

PULSION Medical Systems SE
% Mark Dinger
Senior Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K171620
Trade/Device Name: PiCCO Catheter
Regulation Number: 21 CFR 870.1915
Regulation Name: Thermodilution Probe
Regulatory Class: Class II
Product Code: KRB
Dated: January 15, 2018
Received: January 18, 2018

Dear Mark Dinger:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171620

Device Name
PiCCO Catheter

Indications for Use *(Describe)*
PiCCO Catheters are used as accessories for thermodilution and arterial blood pressure measurement.
PiCCO Catheters are indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. Such as patients in surgical, medical, cardiac and burn specialty units as well as other specialty units where cardiovascular monitoring is desired and patients are undergoing surgical interventions of such magnitude that cardiovascular monitoring is necessary.

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.

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510(K) SUMMARY

Prepared in accordance with 21 CFR Part 807.92

510(k) Number:	K171620
Date Prepared:	12 Jan 2018
Device Owner:	PULSION Medical Systems SE Hans-Riedl-Str. 17 85622 Feldkirchen Germany
Contact Personnel:	Mark Dinger
Title:	Sr. Regulatory Affairs Specialist
Email:	mark.dinger@getinge.com
Phone:	973-709-7691
Fax:	973-909-9954
Trade Name:	PiCCO Catheter
Device Generic Name:	Thermodilution Probe
Classification:	According to 21 CFR 870.1915 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Product code KRB.
Predicate Device:	K072364 PULSION PULSIOCATH THERMODILUTION CATHETERS & ACCESSORIES

Device Description/
Device Function:

The PiCCO Catheter uses a thermistor to measure the blood temperature change during thermodilution. This thermistor is located in one of the two catheter lumen. The second catheter lumen ends in a Luer-Lock for connection to a pressure monitoring kit.
The thermistor is connected to a patient monitor via a dedicated plug.
The placement of the catheter into a large arterial vessel is done using the Seldinger Technique and is intended to use of up to 10 days.
The PiCCO Catheter Sets contain the following parts:

1. PiCCO Catheter,
2. Guidewire with dispenser and advancer,
3. Introducer needles,
4. Dilator (exception: the 3F Set does not include a dilator).

Five PiCCO Catheter models are available which differ in diameter and length. The PiCCO catheter set contains accessories fitting to the respective PiCCO catheter model in size.
The Catheter Set is packed into a preformed blister (PET), sealed with a Tyvek® lid and EtO sterilized.

Scientific Concept Behind:
PiCCO catheter is used with the monitoring system for the measurement of cardiac output by the thermodilution method, measurement of arterial blood pressure, and for cardiac output determination by arterial pulse contour analysis. Additionally the thermodilution measurement allows the determination of the intrathoracic filling volumes and extravascular lung water.
To measure the thermodilution, a known volume of a cold or room-temperature bolus (e.g. normal saline 0.9%) is injected through a central venous catheter. The downstream temperature change is dependent on the flow and the volume through which the cold indicator has passed. A thermodilution curve is recorded by PiCCO Catheter, which also serves for pressure monitoring.
The temperature measurement works as follows:

The thermistor at the tip of the PiCCO catheter provides a temperature dependent resistance. The voltage measurement can detect resistance changes which can be related to temperature changes. The monitor calculates the Cardiac Output according to the Stewart-Hamilton formula using the area under the thermodilution curve. In addition, specific volumes can be calculated by multiplying cardiac output with characteristic time variables of the thermodilution curve.
The parameters can alternatively be displayed as absolute parameters or indexed to the patient´s body characteristics.

Materials Used:

Catheter:	Thermoplastic Polyurethane (TPU), Polyamide (PA), Acrylnitril-Butadien-Styrol (ABS), lead-free solder, printing (Medical Device ink), Nickel Alloy
Dilator:	High Density Polyethylene (HD-PE)
Guidewire:	Stainless steel, Nickel-Titanium Alloy (Nitinol); Protective parts: Polyethylene (PE), Acrylnitril-Butadien-Styrol (ABS), Polypropylene (PP)
Needle:	Stainless steel, Styrene Butadiene Copolymer (SBC) and acrylic-based multipolymer
Primary Packaging:	Glycol-modified polyethylene terephthalate (PETG) and High Density Polyethylene (HD-PE)

Intended Use: PiCCO Catheters are used as accessories for thermodilution and arterial blood pressure measurement.

Indications for Use: PiCCO Catheters are indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. Such as patients in surgical, medical, cardiac and burn specialty units as well as other specialty units where cardiovascular monitoring is desired and patients are undergoing surgical interventions of such magnitude that cardiovascular monitoring is necessary

Technological Characteristics Comparison:

The proposed PiCCO Catheter and the predicate device have the following similarities:

- the same intended use
- the same operating principles
- incorporate the same basic design
- sterilized using the same materials and processes
- the same packaging

The proposed PiCCO Catheter and the predicate device have the following differences:

-
- Clarified indication for use statement and labeling
- Change of material at PiCCO Catheter
- Removed Coating at guidewire

The differences are not considered a significant technological difference. Therefore, the proposed PiCCO Catheter is substantially equivalent to the predicate device.

Safety and Performance:

PULSION Medical Systems development process required that the following activities to be completed during the development of the PiCCO Catheter in support of a substantial equivalence determination:

- Biocompatibility testing
- Performance testing
- Electromagnetic compatibility testing
- Shelf life testing

Biocompatibility Testing:

The biocompatibility evaluation for the PiCCO Catheters 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Chemical Characterization
- Hemolysis (indirect)
- Pyrogenicity

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

- Testing according ISO 594-1:1986, ISO 594-2:1998: Gauging, Liquid Leakage, Air Leakage, Separation Force, Unscrewing Torque, Ease of Assembly, Resistance to Overriding, Stress Cracking
- Shelf Life Testing: Peak Tensile Force measurement before and after aging in accordance to ISO 10555-1:2013
- Guidewire Friction Force Testing

Electrical safety and Electromagnetic compatibility (EMC):
The PiCCO Catheters are non-active accessories for patient monitoring systems. Therefore electrical safety data are not included.
The Electromagnetic Compatibility of the PiCCO Catheters complies with the applicable requirements of IEC 60601-1-2:2007: Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: electromagnetic compatibility – requirements and tests.

Shelf life testing:
Accelerated aging was conducted to demonstrate 60 months (5 years) of shelf life. The study was conducted with increments of 12, 36, and 60 months.
It is concluded that the accelerated data currently available supports a 60 months expiry time from the time of manufacture. Additional real time aging studies with increments of 12, 36 and 60 months are ongoing to support the 60 months expiry dating.

The results of the tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the predicate device.

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Performance Testing Animal: In vivo and in vitro biocompatibility testing has been performed for the changes in PiCCO Catheter.

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 were not required for this device.

Conclusion: The PiCCO Catheter has the same intended use and the same fundamental scientific technology as the predicate device. The performance and other testing established that the PiCCO Catheter meets the same technical and functional requirements and is as safe as effective and performs as well than the legally marketed device. Based upon the information submitted in this Traditional 510(k) premarket notification, PULSION's PiCCO Catheter is substantially equivalent to the currently marketed predicate device (K072364).