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

May 5, 2016

Perimed AB
Jimmy Bakker
Regulatory Affairs Officer
Datavägen 9A
SE-175 43 Järfälla, Sweden

Re: K152930
Trade/Device Name: PeriFlux 6000
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: April 5, 2016
Received: April 13, 2016

Dear Jimmy Bakker:

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,

Shawn W. Forrest -S
2016.05.05 23:12:25 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152930

Device Name
PeriFlux 6000

Indications for Use *(Describe)*
PeriFlux 6000 equipped with PF 6010 is intended for measuring micro-vascular perfusion in skin and muscle in humans. It is also intended for measuring micro-vascular perfusion in all tissues in animals for research purposes.
The PF 6010 is also intended for evaluating tissue response in skin to local heating and providing temperature stabilization of skin at blood perfusion measurement.

PeriFlux 6000 equipped with PF 6050 is intended for measuring the pressure in blood pressure cuffs, to simplify simultaneous measurements of perfusion and pressure when used in conjunction with a laser Doppler perfusion monitor. PeriFlux 6000 equipped with PF 6050 is also intended for Pulse Volume Recording (PVR) on human limbs and digits for diagnosis and evaluation of vascular disease in adults. It is not intended for use on neonates and pregnant women.

PeriFlux 6000 equipped with PF 6040 is intended for continuous non-invasive transcutaneous monitoring of the partial pressures of oxygen and/or carbon dioxide. It is intended for use on neonates, pediatrics, and adults not under gas anesthesia.

(Note: PeriFlux 6000 equipped with PF6040, with an intended use as in the last paragraph, was previously cleared in K131253 and is therefore not part of this submission)

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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PERIMED	Document Type **Traditional 510(k) Notification**	Submission Date **2015-10-02**	Section-Page **6-2/5**
Object/Subject **PeriFlux 6000 – 510(k) Summary**			

Submitter

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Official Correspondent: Maria Prans Liljevret
Contact Person for this submission: Jimmy Bakker

Date prepared: 2 October 2015
Revised: 5 May 2016

Device

Trade Name:	PeriFlux 6000
Common Name:	Modular multichannel system for diagnosis and evaluation of vascular disease
Classification Name:	Cardiovascular blood flowmeter
Classification Regulation:	870.2100
Product Code:	DPW
Panel:	Cardiovascular
Regulatory Class:	II
Type of product:	Finished product

Predicate device

Predicate device No 1 (Primary)

Trade name:	PeriFlux System 5000 PF 5010 LDPM Unit PF 5020 Temp Unit PF 5050 Pressure Unit
510(k) No:	K974285, K932068, K011899
Type of product:	Finished product
Panel:	Cardiovascular

Predicate device No 2

Trade name:	PeriFlux 6000 PF 6040 LDPM Unit
510(k) No:	K131253
Type of product:	Finished product
Panel:	Anesthesiology

Reference device

No reference devices were used in this submission

Device Description

The PeriFlux 6000 is a modular multichannel system that offers several tests for diagnosis and evaluation of vascular disease in one instrument. It consists of a Main Unit (PF 6001), which accommodates up to eight different function units of the same type or of different types enabling simultaneous measurements of several parameters. Currently, one type of unit –*PF 6040 tcpO2/pCO2 Unit*– is available for the US market. Two more units have been developed:

- *PF 6010 LDPM/Temp Unit*
- *PF 6050 Pressure Unit*

The PeriFlux 6000 equipped with PF 6010 function units measures microcirculatory blood flow using Laser Doppler technology. In combination with the PF 6050 function unit to inflate blood pressure cuffs and to register the cuff pressure, it enables a range of different tests, including ankle pressure, toe pressure, skin perfusion pressure (SPP), pulse volume recording (PVR), segmental pressures, heat provocations and post-occlusive reactive hyperemia (PORH).
In Laser Doppler Perfusion Monitoring, an optical fibre leads light generated by a laser to the LDPM probe tip, which rests against the tissue. The beam of light will enter the tissue and become scattered. Blood cells moving within the volume illuminated by the beam will cause the light to change frequency. This change in frequency is called a Doppler shift and it is used to calculate the blood flow in the illuminated tissue.

Indications for Use

PF 6010 LDPM/Temp Unit

PeriFlux 6000 equipped with PF 6010 is intended for measuring micro-vascular perfusion in skin and muscle in humans. It is also intended for measuring micro-vascular perfusion in all tissues in animals for research purposes.
The PF 6010 is also intended for evaluating tissue response in skin to local heating and providing temperature stabilization of skin at blood perfusion measurement.

PF 6040 tc*p*O_2/CO_2 Unit

PeriFlux 6000 equipped with PF 6040 is intended for continuous non-invasive transcutaneous monitoring of the partial pressures of oxygen and/or carbon dioxide.
It is intended for use on neonates, pediatrics, and adults not under gas anesthesia.

PF 6050 Pressure Unit

PeriFlux 6000 equipped with PF 6050 is intended for measuring the pressure in blood pressure cuffs, to simplify simultaneous measurements of perfusion and pressure when used in conjunction with a laser Doppler perfusion monitor.
PeriFlux 6000 equipped with PF 6050 is also intended for Pulse Volume Recording

(PVR) on human limbs and digits for diagnosis and evaluation of vascular disease in adults.
It is not intended for use on neonates and pregnant women.

(*Note: PeriFlux 6000 equipped with PF 6040, with an intended use as described under "PF 6040 tcpO2/CO2 Unit", was previously cleared in K131253 and is therefore not part of this submission*)

Environment of use

The PeriFlux 6000 instrument is intended for professional use in a hospital environment, laboratory environment and in a hospital intensive care unit environment.

Comparison of technological characteristics with the predicate devices

There are no technological differences between the instrument approved in K131253 and the current Periflux 6000 when equipped with PF 6040 besides the ability to host the other function units. Predicate device No 2 is listed for completeness and will not be discussed further. The Periflux 6000 and the primary predicate device have Laser Doppler Perfusion Monitoring as a technological principle. It is based on measuring the Doppler shift of laser light scattered in the tissue as a measure of micro-vascular blood flow.
At high level, the Periflux 6000 and the primary predicate device are based on the following same technological elements:

- An infrared laser with laser class 1 (IEC 60825-1:2007, 21 CFR 1040.10 and 1040.11)
- Measurement through optical fibre probes.
- Temperature measurement and control in the probe possible
- Measurement and control of pressure in blood pressure cuffs
- Possibility to combine different function units in one device

The following technological differences exist between the PeriFlux 6000 and the primary predicate device:

- Use of an SVGA display with touch screen operation
- Up to 8 function units in one device (compared to 4 in primary predicate)
- Laser Doppler Perfusion Monitoring and probe heating combined in one function unit
- Perfusion calculated from a larger frequency bandwidth.
- 6 individually controlled cuff connectors and a built-in pump.

Summary of Performance Tests

Performance Testing – Bench

Laser Doppler Perfusion Monitoring is an intricate measurement, involving more electronics and calculations than measurements of the other parameters. Also, the PF

6010 measures over a higher frequency bandwidth than the PF 5010. We have therefore tested how the clinically relevant parameter, blood perfusion, correlates between these two systems. The tests show that the signals correlate very well between the two systems and that they can be regarded as equivalent.

Performance Testing – Animal

No performance tests on animals are submitted.

Performance Testing – Clinical

No clinical performance tests are submitted.

Conclusion

The discussion of similarities and differences between the new device and the predicate device shows that the new device is similar to the predicate device in most of the relevant properties. The intended use of the devices is the same. A few differences in technological characteristics have been found and the discussion concludes that these differences do not raise different questions of safety and effectiveness, nor do they adversely affect safety and effectiveness. The PeriFlux 6000 simply follows the state of the art in standards and available technology to create a safe, effective and convenient device. Temperature and pressure are measured using the same technology and use the same type of sensors in PeriFlux 6000 as in PeriFlux System 5000 and comparative testing shows that Laser Doppler Perfusion measurements on these two systems can also be regarded as equivalent.
The conclusion is that the new device PeriFlux 6000 is substantially equivalent to the predicate device PeriFlux System 5000.