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|   | <b>Response to Additional Information Request<br/>for K131253</b> | 2013-04-26               | 6-2/6        |
| Object/Subject<br><b>PeriFlux 6000 – 510(k) Summary</b>                           |   |                          |              |

**Submitter's Name & Address**

Perimed AB  
 Datavägen 9A  
 SE-175 43 Järfälla, Sweden  
 Tel: (011) 46 8 580 119 90  
 Fax: (011) 46 8 580 100 28  
 Official Correspondent: Maria Liljevret  
 Contact Person for this submission: Maria Liljevret

OCT 22 2013

**Date of Summary**

The Summary was prepared 26<sup>th</sup> of April 2013 and revised 23<sup>rd</sup> of October 2013.

**Device Information**

Trade name: PeriFlux 6000  
 Type of product: Finished product  
 Panel: Anesthesiology

Common Name, Classification Name, Class & Classification Regulation:


| Common Name  | Classification Name   | Class | Classification Regulation | Product Code      |
|--|---|-------|---------------------------|-------------------|
| Transcutaneous pO <sub>2</sub> /pCO <sub>2</sub> monitoring system | Cutaneous carbon dioxide (PcCO <sub>2</sub> ) monitor<br>Cutaneous oxygen (PcO <sub>2</sub> ) monitor | II    | 868.2480                  | LKD,<br>LPP, KLK, |

**Predicate Device Information**

**Predicate Device No 1**  
 Trade name: TCM4 Monitoring System  
 510(k) No: K043003  
 Type of product: Finished product  
 Panel: Anesthesiology

Common Name, Classification Name, Class & Classification Regulation:

| Common Name  | Classification Name  | Class | Classification Regulation | Product Code     |
|--|--|-------|---------------------------|------------------|
| Transcutaneous pO <sub>2</sub> /pCO <sub>2</sub> /SpO <sub>2</sub> / pulse monitoring system | Cutaneous carbon dioxide (PcCO <sub>2</sub> ) monitor,<br>Cutaneous oxygen (PcO <sub>2</sub> ) monitor | II    | 868.2480                  | LKD,<br>LPP, KLK |

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| Object/Subject<br><b>PeriFlux 6000 – 510(k) Summary</b>                           |   |                          |              |

**Predicate Device No 2**

Trade name: TCM400  
510(k) No: K001866  
Type of product: Finished product  
Panel: Anesthesiology

Common Name, Classification Name, Class & Classification Regulation:

| Common Name                                      | Classification Name                          | Clas | Classification Regulation | Product Code |
|--|--|------|---------------------------|--------------|
| Transcutaneous pO <sub>2</sub> monitoring system | Cutaneous oxygen (PcO <sub>2</sub> ) monitor | II   | 868.2500                  | LPP          |

**Device Description**

PeriFlux 6000 is a transcutaneous oxygen/carbon dioxide (tcpO<sub>2</sub>/CO<sub>2</sub>) monitor, and consists of a main unit, PF 6001, that can be equipped with 1 to 8 PF 6040 function units. An electrode E5250 or E5280 is connected to each function unit and is applied to a patient’s skin. Electrode E5250 consists of a Clark sensor and is used for O<sub>2</sub> measurement. Electrode E5280 is a combined Clark sensor and Stow-Severinghaus-type sensor, and is used for both O<sub>2</sub> and CO<sub>2</sub> measurement. Upon measurement, the electrode is heated to make the skin permeable to gas diffusion, which allows O<sub>2</sub> and CO<sub>2</sub> to diffuse through the skin into the sensor. The instrument is operated from its touch screen interface and allows the users to record, analyze and report tcpO<sub>2</sub> and tcpCO<sub>2</sub> values.

**Intended Use of the Device**

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.

**Table of Device Similarities and Differences to Predicate Devices**

|   | New device   | Predicate Device No 1  | Predicate Device No 2   | Similar/<br>Different* |
|---|--|--|---|------------------------|
| Property:   | PeriFlux 6000  | TCM4   | TCM400  |                        |
| 510(k) number   | New submission   | K043003  | K001866   | -                      |
| 510(k) holder   | Perimed AB   | Radiometer   | Radiometer  | -                      |
| Intended use (Indications for use, target population) | PeriFlux 6000 equipped with PF 6040 is intended for continuous non-invasive transcutaneous monitoring of the partial pressures of oxygen | The TCM4 Monitoring System is intended for continuous transcutaneous monitoring of oxygen and carbon dioxide | The TCM400 system is a device that uses up to six non-invasive electrodes placed on the patient's skin and that is intended to record | Similar                |



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**PeriFlux 6000 – 510(k) Summary**

|   | New device   | Predicate Device No 1   | Predicate Device No 2  | Similar/<br>Different*                                |
|---|--|---|--|---|
| Property                                    | PeriFlux 6000  | TCM4  | TCM400   |   |
|   | and/or carbon dioxide. It is intended for use on neonates, pediatrics, and adults not under gas anesthesia.  | partial pressures. It is indicated for use on neonates, pediatrics, and adults not under gas anesthesia.  | transcutaneous oxygen partial pressures in adults not under gas anesthesia.  |   |
| Environment of use                          | In hospital environment, laboratory environment and in hospital intensive care unit environment.   | In hospital/clinical environment.   | Unspecified  | Similar   |
| Measurement principle                       | Clark-type O <sub>2</sub> sensor<br>Stow-Severinghaus-type CO <sub>2</sub> sensor  | Clark-type O <sub>2</sub> sensor<br>Stow-Severinghaus-type CO <sub>2</sub> sensor   | Clark-type O <sub>2</sub> sensor   | Similar   |
| Maximum number of electrodes                | 8 electrodes   | 1 electrode   | 6 electrodes   | Different   |
| Accepted electrode models                   | Electrode E5250 is used for O <sub>2</sub> measurement. Electrode E5280 is used for combined O <sub>2</sub> and CO <sub>2</sub> measurement. Both electrodes are manufactured and packaged by Radiometer under Radiometer label. | Electrode E5280 or E5480 is used for combined O <sub>2</sub> and CO <sub>2</sub> measurement. Electrode E5260 is used for CO <sub>2</sub> measurement. All electrodes are manufactured and packaged by Radiometer under Radiometer label. | Electrode E5250 is used for O <sub>2</sub> measurement. Electrode E5250 is manufactured and packaged by Radiometer under Radiometer label. | Similar   |
| Measurement Range                           | <u>Combined electrode:</u><br>tcpO <sub>2</sub> : 0 - 800 mmHg<br>tcpCO <sub>2</sub> : 5 - 100 mmHg<br><u>Single tcpO<sub>2</sub> electrode:</u><br>tcpO <sub>2</sub> : 0 - 1999 mmHg<br>-<br>-<br>-                             | <u>Combined electrode:</u><br>tcpO <sub>2</sub> : 0 - 800 mmHg<br>tcpCO <sub>2</sub> : 5 - 100 mmHg<br>-<br>-<br><u>Single tcpCO<sub>2</sub> electrode:</u><br>tcpCO <sub>2</sub> : 5 - 100 mmHg  | -<br>-<br>-<br><u>Single tcpO<sub>2</sub> electrode:</u><br>tcpO <sub>2</sub> : 0 - 1999 mmHg<br>-<br>-<br>-                               | Similar   |
| Safety Standards                            | IEC 60601-1:2005<br>IEC 60601-1-2:2007<br>-<br>IEC 60601-1-8:2006<br>IEC 60601-2-23:2011   | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-4<br>IEC 60601-1-8<br>IEC 60601-2-23  | IEC 60601-1<br>IEC 60601-1-2<br>-<br>-<br>IEC 60601-2-23   | Similar<br>Similar<br>Different<br>Similar<br>Similar |
| Performance Standards/<br>Guidance Document | IEC 60601-1-8:2006<br>IEC 60601-2-23:2011<br>-<br>Special Controls<br>Guidance Document:   | IEC 60601-1-8<br>IEC 60601-2-23<br>IEC 60601-3-1<br>Special Controls<br>Guidance Document:  | -<br>IEC 60601-2-23<br>IEC 60601-3-1<br>Special Controls<br>Guidance Document:   | Similar<br>Similar<br>Different<br>Similar            |

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| <b>PeriFlux 6000 – 510(k) Summary</b>   |   |                          |              |

|          | New device   | Predicate Device No 1  | Predicate Device No 2  | Similar/<br>Different* |
|----------|--|--|--|------------------------|
| Property | PeriFlux 6000  | TCM4   | TCM400   |                        |
|          | Cutaneous Carbon Dioxide (tcpCO <sub>2</sub> ) and Oxygen (tcpO <sub>2</sub> ) Monitors; Guidance for Industry and FDA, 2002 | Cutaneous Carbon Dioxide (tcpCO <sub>2</sub> ) and Oxygen (tcpO <sub>2</sub> ) Monitors; Guidance for Industry and FDA, 2002 | Cutaneous Carbon Dioxide (tcpCO <sub>2</sub> ) and Oxygen (tcpO <sub>2</sub> ) Monitors; Guidance for Industry and FDA, 2002 |                        |

\* Similar is stated for a property when the table clearly shows a significant similarity between the new device and either both the predicate devices or one of the two predicate devices. Different is stated when a justification is needed for claiming equivalency.


### ***Summary of Technological Characteristics of Device and Predicate Device***

The new device has the same overall design and size as the predicate devices. The intended use of the new device is a combination of both predicate devices. The new device uses the same measuring technology as the predicate devices, a Clark sensor (tcpO<sub>2</sub>) and a Stow-Severinghaus-type sensor (tcpCO<sub>2</sub>). Electrodes of the same brand and model as for the predicate devices are used with the new device, E5250 (tcpO<sub>2</sub>) and E5280 (tcpO<sub>2</sub>/tcpCO<sub>2</sub>) manufactured and packaged by Radiometer under Radiometer label. As a consequence, both the pressure measurements and temperature ranges of the electrodes are identical for the new device as the predicate devices. The new device can employ a combination of up to eight electrodes, contrary to the predicate devices (one electrode for TCM4 and six electrodes for TCM400). Both the new device and the predicate devices contain alarm functionality that includes both technical and physiological alarms.

### ***Summary of Safety and Performance Tests***

To ensure that the new device, PeriFlux 6000 equipped with PF 6040, is safe and effective for its intended use, it has been tested to the requirements of the *Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (tcpCO<sub>2</sub>) and Oxygen (tcpO<sub>2</sub>) Monitors; Guidance for Industry and FDA (December 13, 2002)*, as well as the following international consensus standards:

- *IEC 60601-1:2005*  
Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- *IEC 60601-1-2:2007*  
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- *IEC 60601-2-23:2011*

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| <b>PeriFlux 6000 – 510(k) Summary</b>   |   |                          |              |

Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

- *IEC 60601-1-8:2006*  
General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

A detailed analysis of the fulfilled safety and performance standards between the new device and the predicate devices show that the new device fulfills the same safety and performance requirements as the predicate devices, with the following justification: Standard *IEC 60601-1-4* has been included in the updated version of standard *IEC 60601-1:2005*, and standard *IEC 60601-3-1* has been included in the updated version of standard *IEC 60601-2-23:2011*, both of which the new device has been tested against and fully complies with.

### ***Conclusions***

The results of the safety and performance testing show that the PeriFlux 6000, equipped with PF 6040, is a modern transcutaneous oxygen/carbon dioxide monitor that meets the performance requirements and is equipped with the required safety mechanisms. Further, the analysis fully justifies substantial equivalence to both predicate devices.



October 22, 2013

Perimed AB  
Maria Liljevret  
Quality Assurance and Regulatory Affairs Manager  
Datavagen 9A  
SE-175 43 Jarfalla, Sweden

Re: K131253

Trade/Device Name: PeriFlux System 6000  
Regulation Number: 21 CFR 868.2480  
Regulation Name: Cutaneous Carbon Dioxide (P<sub>c</sub>CO<sub>2</sub>) Monitor  
Regulatory Class: Class II  
Product Code: LKD, KLK, LPP  
Dated: September 20, 2013  
Received: September 23, 2013

Dear Ms. Liljevret:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,




Tejashri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID

FOR

Kwame Ulmer, M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

|   |                                 |                 |              |
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|  | Document Type                   | Submission Date | Section-Page |
|   | Abbreviated 510(k) Notification | 2013-04-26      | 5-2/2        |
| Object/Subject<br>PeriFlux 6000 – Indications for Use                             |                                 |                 |              |

***Indications for Use***

510(k) Number (if known): K131253

**Device Name:**

PeriFlux 6000

**Indications for Use:**

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.

Prescription Use Yes AND/OR Over-The-Counter Use No  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan Patel  
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