June 20, 2017

Cosmed S.r.l.
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
Rome, 00153 IT

Re: K162515
Trade/Device Name: COSMED K5 Wearable Metabolic Technology
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: Class II
Product Code: BZC
Dated: May 17, 2017
Received: May 22, 2017

Dear Roger Gray:

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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
    General Hospital, Respiratory,
    Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The COSMED K5 Wearable Metabolic Technology is a device designed to measure cardio-respiratory and metabolic functions during stress testing, rehabilitation, sports medicine and other related activities, performed in professional healthcare facilities only. The system is not intended for Home Use.

The main measurements reported by the system are Oxygen Uptake, Carbon Dioxide production, Ventilation, Heart Rate and Energy Expenditure.

K5 is intended to use with adults and children over the age of 14 years.

It is to be used by physicians or by trained personnel on a physician responsibility.

The system and its accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals. It must not be intended as a monitoring device, nor as a sole means for determining a patient’s diagnosis but for the purpose of assisting the clinician in the diagnosis of cardio-pulmonary diseases.

Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)
510(k) Summary

Device Name: COSMED K5 Wearable Metabolic Technology

Type of 510(k) submission: Traditional

Date of submission: 12 June 2017

Manufacturer: Cosmed Srl
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Fax: +39 06 931 4580

FDA Establishment Reg. Number: 8021084

510(k) Owner and Submitter: Cosmed Srl
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Italy

Owner/Operator Reg. Number: 8021084

510(k) Application Correspondent: Mr Roger Gray
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Phone: +39 06 578 2665
Fax: +39 06 574 3786
Email: rgray@donawa.com

FDA Product Code: BZC

FDA Regulation Number: 21 CFR 868.1880

FDA Classification Name: Calculator, Pulmonary Function Data

Classification Panel: Anesthesiology

Common Name: Pulmonary Function Data Calculator

FDA Classification: Class II

Submission Type: 510(k)

Indications for Use:
The COSMED K5 Wearable Metabolic Technology is a device designed to measure cardio-respiratory and metabolic functions during stress testing, rehabilitation, sports medicine and other related activities, performed in professional healthcare facilities only. The system is not intended for Home Use.
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**Device Description:**
The COSMED K5 Wearable Metabolic Technology is a portable unit, designed for the measurement of resting and exercise metabolism in the laboratory, utilizing international measurement guidelines published by relevant scientific societies. The K5 consists of the following main parts:

- Main portable unit
- Optional Bluetooth receiver
- PC software
- Face mask with head cap
- Turbine flowmeter with optoelectronic reader and wind cover
- Harness
- Heart rate monitor belt
- O2 sensor
- Battery charger + batteries
- AC/DC adapter
- USB cable
- Carrying case
- Optional pressure regulator for calibration

The K5 system is intended to be used the laboratory, by either direct connection or by telemetry. The system offers both ‘breath-by-breath’ and ‘mixing chamber’ operational modes.

**Performance data:**
Measurement of exercise metabolism consists of collecting during physical activities (e.g. running, cycling, rowing, etc.) a number of physiological variables (including breathing flow, exhaled O2 fraction, exhaled CO2 fraction, heart rate) and environmental signals (ambient temperature, pressure and humidity) in order to calculate the following main parameters:

- VO2 (ml/min) Oxygen Uptake, known also as Oxygen Consumption
- VCO2 (ml/min) Carbon Dioxide production
- VE (l/min) Minute Ventilation
- HR (1/min) Heart Rate
- RQ (---) Respiratory Quotient

Measurement of resting metabolism consists of measuring at rest the following main parameters:

- VO2 (ml/min) Oxygen Uptake, known also as Oxygen Consumption
- VCO2 (ml/min) Carbon Dioxide production
- RQ (---) Respiratory Quotient
- EE (Kcal/day) Energy Expenditure
Non-clinical testing:
Subject device non-clinical testing confirms that the device meets its specification, including the requirements of relevant standards:

- Electrical safety in accordance with IEC 60601-1:2005
- EMC in accordance with IEC 60601-1-2:2007
- Accuracy validation (Vt, RF, VO2, VCO2)
- Coexistence testing (FCC Part 15)
- Protection provided by enclosure (IEC 60529:2013)

In relation to biocompatibility, all of the K5 components that are either intended to contact the patient or may come into contact with the patient during use have been previously assessed for their biocompatibility, as appropriate for the nature of their body contact and contact duration, by FDA within already-cleared 510(k) submissions.

The results of the above testing, together with previous FDA clearances, assist in the demonstration of substantial equivalence of the subject device with the predicate device.

**Substantial equivalence**
The predicate device selected for comparison with the Cosmed K5 Wearable Metabolic Technology is:

Predicate Device: Jaeger Oxycon Mobile
Sponsor: SensorMedics, Inc.
510(k) Number: K023120
Clearance Date: 12 November 2003
FDA Product Code: BZC
Classification Name: Calculator, Pulmonary Function Data
Regulation No: 21 CFR 868.1880
Class: II

**Predicate device comparison table:**
Table 1 provides evidence of substantial equivalence of the subject device with the selected predicate device.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Subject device</th>
<th>Predicate device</th>
<th>Similarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>K5 Wearable Metabolic Technology</td>
<td>Jaeger Oxycon Mobile</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Manufacturer</td>
<td>Cosmed</td>
<td>SensorMedics</td>
<td>N/A</td>
</tr>
<tr>
<td>510(k) Reference</td>
<td>This submission</td>
<td>K023120</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA Product Code</td>
<td>BZC</td>
<td>BZC</td>
<td>Same</td>
</tr>
<tr>
<td>FDA Classification Name</td>
<td>Calculator, Pulmonary Function Data</td>
<td>Calculator, Pulmonary Function Data</td>
<td>Same</td>
</tr>
<tr>
<td>FDA Regulation Number</td>
<td>868.1880</td>
<td>868.1880</td>
<td>Same</td>
</tr>
<tr>
<td>Device description</td>
<td>A portable cardiopulmonary function testing system offering breath-by-breath and sample mixing options, with wireless telemetry</td>
<td>A portable cardiopulmonary function testing system offering breath-by-breath sampling and wireless telemetry</td>
<td>Similar</td>
</tr>
</tbody>
</table>
### Table 1: Predicate device comparison table

<table>
<thead>
<tr>
<th>Feature</th>
<th>Subject device</th>
<th>Predicate device</th>
<th>Similarity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for use</strong></td>
<td>The COSMED K5 Wearable Metabolic Technology is a device designed to measure cardio-pulmonary function mobile test system is a device which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The system is not intended for Home Use.</td>
<td>The Jaeger OXYCON MOBILE pulmonary function mobile test system allows the use of telemetry for the monitoring of metabolic parameters. The OXYCON MOBILE system is intended to use with adults and children over the age of 14 years.</td>
<td>Substantially equivalent</td>
</tr>
<tr>
<td></td>
<td>The main measurements reported by the system are Oxygen Uptake, Carbon Dioxide production, Ventilation, Heart Rate and Energy Expenditure. K5 is intended to use with adults and children over the age of 14 years. It is to be used by physicians or by trained personnel on a physician responsibility. The system and its accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals. It must not be intended as a monitoring device, nor as a sole means for determining a patient’s diagnosis but for the purpose of assisting the clinician in the diagnosis of cardio-pulmonary diseases.</td>
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</tr>
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<td>A portable cardiopulmonary function testing system offering breath-by-breath sampling and wireless telemetry</td>
<td>Similar</td>
</tr>
<tr>
<td><strong>User Population</strong></td>
<td>Adults and children over the age of 14 years</td>
<td>Adults and children over the age of 14 years</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Use environment</strong></td>
<td>Professional healthcare facilities</td>
<td>Indoor and outdoor use</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Device measurements</strong></td>
<td>Cardiorespiratory functions during stress testing, rehabilitation, sport medicine and other related activities</td>
<td>Cardiorespiratory functions during stress testing, rehabilitation, sport medicine and other related activities</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Measurement mode(s)</strong></td>
<td>Breath by breath and mixing chamber</td>
<td>Breath by breath only</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Output parameters</strong></td>
<td>Ergospirometric key parameters such as ventilation, VO2, VCO2, anaerobic threshold, RQ, HR, VE/VO2, VE/VCO2.</td>
<td>Ergospirometric key parameters such as ventilation, VO2, VCO2, anaerobic threshold, RQ, HR, VE/VO2, VE/VCO2.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Major separate system components</strong></td>
<td>K5 unit, flowmeter, masks, receiver USB stick (to PC)</td>
<td>Oxycon unit (2 pieces), flowmeter, masks, receiver unit (to PC)</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Flowmeter technology</strong></td>
<td>Bi-directional turbine</td>
<td>Bi-directional turbine</td>
<td>Same</td>
</tr>
<tr>
<td><strong>O₂ sensor technology</strong></td>
<td>Electrochemical</td>
<td>Electrochemical</td>
<td>Same</td>
</tr>
<tr>
<td><strong>CO₂ sensor technology</strong></td>
<td>Infrared</td>
<td>Thermal conductivity</td>
<td>Different</td>
</tr>
<tr>
<td><strong>Barometric pressure sensor technology</strong></td>
<td>Piezo-resistive</td>
<td>Piezo-resistive</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Telemetry</strong></td>
<td>Bluetooth, bi-direction</td>
<td>2401-2495 MHz, bi-direction</td>
<td>Different</td>
</tr>
</tbody>
</table>
The subject device and the predicate device have many identical or similar properties or features. The differences that exist and are identified in the above table include:

- Measurement mode(s)
- Major separate system components
- CO₂ sensor technology
- Use environment
- Telemetry
- User interface
- Dimensions
- Measurement range
- Measurement accuracy

None of the identified differences introduce new aspects of safety or effectiveness.

12.4 Conclusion

Based on the information contained within this submission, it is concluded that the COSMED K5 Wearable Metabolic Technology is substantially equivalent to the identified predicate device already in interstate commerce within the USA.