DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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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

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)*
K162515

Device Name
COSMED K5 Wearable Metabolic Technology

Indications for Use *(Describe)*
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)*

☒ 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

Device Name:	COSMED K5 Wearable Metabolic Technology
Type of 510(k) submission:	Traditional
Date of submission:	12 June 2017
Manufacturer:	Cosmed Srl Vi dei Piani di Monte Savello 37 Albano Laziale 00041 Rome Italy
Phone: **Fax:**	+39 06 931 5492 +39 06 931 4580
FDA Establishment Reg. Number:	8021084
510(k) Owner and Submitter:	Cosmed Srl Vi dei Piani di Monte Savello 37 Albano Laziale 00041 Rome Italy
Owner/Operator Reg. Number:	8021084
510(k) Application Correspondent:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 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.

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.

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, VO_2, VCO_2)
- 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 1: Predicate device comparison table

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

Table 1: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
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.	The Jaeger OXYCON MOBILE 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 OXYCON MOBILE 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.	Substantially equivalent
Device description	A portable cardiopulmonary function testing system offering breath-by-breath and sample mixing options, with wireless telemetry	A portable cardiopulmonary function testing system offering breath-by-breath sampling and wireless telemetry	Similar
User Population	Adults and children over the age of 14 years	Adults and children over the age of 14 years	Same
Use environment	Professional healthcare facilities	Indoor and outdoor use	Different
Device measurements	Cardiorespiratory functions during stress testing, rehabilitation, sport medicine and other related activities	Cardiorespiratory functions during stress testing, rehabilitation, sport medicine and other related activities	Same
Measurement mode(s)	Breath by breath and mixing chamber	Breath by breath only	Different
Output parameters	Ergospirometric key parameters such as ventilation, VO2, VCO2, anaerobic threshold, RQ, HR, VE/VO2, VE/VCO2.	Ergospirometric key parameters such as ventilation, VO2, VCO2, anaerobic threshold, RQ, HR, VE/VO2, VE/VCO2.	Same
Major separate system components	K5 unit, flowmeter, masks, receiver USB stick (to PC)	Oxycon unit (2 pieces), flowmeter, masks, receiver unit (to PC)	Different
Flowmeter technology	Bi-directional turbine	Bi-directional turbine	Same
O_2 sensor technology	Electrochemical	Electrochemical	Same
CO_2 sensor technology	Infrared	Thermal conductivity	Different
Barometric pressure sensor technology	Piezo-resistive	Piezo-resistive	Same
Telemetry	Bluetooth, bi-directional	2401-2495 MHz, bi-directional	Different

Table 1: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
User interface	LCD touchscreen plus PC keyboard and mouse	PC Keyboard and mouse	Different
PC Software	Windows based application	Windows based application	Same
Biocompatibility	All patient contact components are biocompatible and used in already legally marketed devices with the same intended use	All patient contact components are biocompatible and used in already legally marketed devices with the same intended use	Same
Sterility	Non-sterile	Non-sterile	Same
Anatomical sites	Patient's mouth, through face mask	Patient's mouth, through face mask	Same
Energy used	External or internal power supply	External or internal power supply	Same
Energy delivered	No energy delivered to patient	No energy delivered to patient	Same
Standards: Safety	IEC 60601-1: class II / Internal Electric Power Source - type BF	IEC 60601-1: class II / Internal Electric Power Source - type BF	Same
Battery	Lithium-Ion, rechargeable	Lithium-Ion, rechargeable	Same
Dimensions	1 unit 174 x 111 x 64 mm	2 units 126 x 96 x 41mm	Different
Weight	900g (31.7 oz)	950g (33.4 oz)	Similar
Measurement Range	Ventilation: 0-300 l/min VO_2: 0.1-7 l/min VCO_2: 0.1-7 l/min	Ventilation: 0-300 l/min VO_2: 0-7 l/min VCO_2: 0-7 l/min	Different
Measurement Accuracy	Ventilation: <2% or 50 ml/min VO2: <3% VCO2: <3%	Ventilation: <2% or 50 ml/min VO2: <3% or 50 ml/min VCO2: <3% or 50 ml/min	Different

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
- CO_2 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.