February 6, 2020

Cosmed Srl
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania 10
Rome, 00153
Italy

Re: K190800
Trade/Device Name: Cosmed Q-NRG & Q-NRG+ Portable Metabolic Monitors
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: BTY
Dated: January 6, 2020
Received: January 9, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190800

Device Name
Cosmed Q-NRG & Q-NRG+ Portable Metabolic Monitors

Indications for Use *(Describe)*
The Q-NRG & Q-NRG+ Portable Metabolic Monitors are indicated for the measurement of Resting Energy Expenditure (REE) for spontaneously breathing and (Q-NRG+ only) ventilated patients, within the following populations:
- Spontaneously breathing subjects >15 kg (33 lb) when using a canopy;
- Spontaneously breathing subjects age >6 and >10 kg (22 lb) when using a face mask;
- Ventilated subjects age >10 and >10 kg (22 lb).

The Q-NRG & Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only (limited to ICUs for ventilated patients).

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

510(k) Reference:	K190800
Device Name:	Cosmed Q-NRG & Q-NRG+ Portable Metabolic Monitors
Type of 510(k) submission:	Traditional
Date of submission:	5 February 2020
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:	BTY
FDA Regulation Number:	21 CFR 868.1890
FDA Classification Name:	Calculator, Pulmonary Function Data
Classification Panel:	Anesthesiology
Common Name:	Calculator, predicted values, pulmonary function; Ventilator, continuous, facility use
FDA Classification:	Class II
Submission Type:	510(k)

Indications for Use:
The Q-NRG & Q-NRG+ Portable Metabolic Monitors are indicated for the measurement of Resting Energy Expenditure (REE) for spontaneously breathing and (Q-NRG+ only) ventilated patients, within the following populations:
- Spontaneously breathing subjects >15 kg (33 lb) when using a canopy;
- Spontaneously breathing subjects age >6 and >10 kg (22 lb) when using a face mask;
- Ventilated subjects age >10 and >10 kg (22 lb).

The Q-NRG & Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only (limited to ICUs for ventilated patients).

Device Description:
The Q-NRG and Q-NRG+ devices are Portable Metabolic Monitors, designed for the measurement of resting energy expenditure (REE) in both spontaneously breathing and mechanically ventilated patients.

The two versions of the product are detailed in Table 1.

Table 1: Device versions		
Measurement Modes	**Q-NRG**	**Q-NRG+**
Ventilator assisted	Not available	Standard
Canopy	Standard	Option
Face mask	Option	Option

The Q-NRG and Q-NRG+ devices comprise the parts identified in Table 2.

Table 2: Device components		
Item	**Q-NRG**	**Q-NRG+**
Main device	Standard	Standard
Canopy mode accessories	Standard	Option
Ventilation mode accessories	Not available	Option
Face mask mode accessories	Option	Option
PC Software (OMNIA)	Option	Option
Clamp for pole/rail with VESA mounting plate	Option	Option
Calibration syringe	Option	Option
Calibration Cylinder and Regulator	Option	Option

Performance data:
The essential performance of the Q-NRG and Q-NRG+ devices is to measure or calculate:

- REE (kcal/day) Resting Energy Expenditure
- VO2 (ml/min) Oxygen Uptake *
- VCO2 (ml/min) Carbon Dioxide production
- RQ (---) Respiratory Quotient

* Average resting oxygen uptake for a healthy individual is 3.5 ml/Kg/min (1 MET - Metabolic Equivalent).

The Q-NRG and Q-NRG+ are to be used by physicians or by trained personnel under the responsibility of a physician.

The Q-NRG and Q-NRG+ are not intended for long term use or as continuous monitoring devices for surveillance of vital physiological processes.

Non-clinical testing:
Non-clinical testing of the Q-NRG and Q-NRG+ includes:

- Electrical safety
- Electromagnetic Compatibility (EMC)
- Accuracy validation
- Coexistence testing
- Biocompatibility
- Reprocessing validation
- Human factors

More detail of the non-clinical testing is provided in Table 3.

Table 3: Non-clinical testing	
Test type	**Reference**
Electrical safety	ANSI/AAMI ES 60601-1:2005/®2012 + A1:2012 + C1:2009/®2012 + A2:2010/®2012, FDA recognition #19-4
EMC	IEC 60601-1-2:2014, FDA recognition #19-8
	ETSI EN 301 489-17 v3.2.0 draft
	ETSI EN 301 489-1 v2.2.0 draft
	FCC Part 15 par. 107, 109
	ICES-003 Issue 6: January 19, 2016, updated April 2017
Accuracy validation	Mask Measurement Accuracy, according to internal validation protocol
	Canopy Measurement Accuracy, according to internal validation protocol
	Ventilator Measurement Accuracy, according to internal validation protocol
Coexistence testing	Coexistence testing between Q-NRG/Q-NRG+ Bluetooth and other environmental wireless disturbances (i.e. Network Wi-Fi), according to the indications reported in *S. Seidman, N. LaSorte, "An Experimental Method for Evaluating Wireless Coexistence of a Bluetooth Medical Device," IEEE EMC Magazine, October 2014*
Biocompatibility	ISO 10993-1:2009, FDA recognition #2-220
	ISO 10993-5:2009, FDA recognition #2-245
	ISO 10993-10:2010, FDA recognition #2-174
	ISO 18562-2:2017, FDA recognition #1-135
	ISO 18562-3:2017, FDA recognition #1-136
	ISO 18562-4:2017, FDA recognition #1-137
	FDA Guidance Use of International Standard ISO 10993-1, June 16, 2016
Reprocessing validation	According to internal validation protocol
Human Factors	According to internal verification protocol

The results of the above testing assist in demonstration of substantial equivalence of the subject device with the predicate device, as many of the same standards have been used.

Substantial equivalence
The predicate device selected for comparison with the Q-NRG and Q-NRG+ Portable Metabolic Monitors is:

Predicate Device:	Quark RMR Metabolic Cart
Sponsor:	Cosmed Srl, Italy
510(k) Number:	K120146
Clearance Date:	11 December 2012
FDA Product Code:	BTY
Classification Name:	Predictive Pulmonary-Function Value Calculator
Regulation No:	21 CFR 868.1890
Class:	II

Predicate device comparison table:
Table 4 provides evidence of substantial equivalence of the subject device with the selected predicate device.

Table 4: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Device name	Q-NRG & Q-NRG+ Portable Metabolic Monitors	Quark RMR Metabolic Cart	N/A

Table 4: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Device Manufacturer	Cosmed Srl, Italy	Cosmed Srl, Italy	Same
510(k) Reference	This submission	K120146	N/A
FDA Product Code	BTY	BTY	Same
FDA Classification Name	Calculator, Pulmonary Function Data	Calculator, Pulmonary Function Data	Same
FDA Regulation Number	21 CFR 868.1890	21 CFR 868.1890	Same
Device description	Portable metabolic monitors, designed for the measurement of resting energy expenditure (REE) in both spontaneously breathing and mechanically ventilated patients	Metabolic cart for gas exchange analysis (VO2, VCO2) either during resting or exercise. either with spontaneously breathing subjects (at rest and during exercise) or mechanically assisted patients	Similar, subject device is not indicated for exercising patients
Indications for use	The Q-NRG & Q-NRG+ Portable Metabolic Monitors are indicated for the measurement of Resting Energy Expenditure (REE) for spontaneously breathing and (Q-NRG+ only) ventilated patients, within the following populations: - Spontaneously breathing subjects >15 kg (33 lb) when using a canopy; - Spontaneously breathing subjects age >6 and >10 kg (22 lb) when using a face mask; - Ventilated subjects age >10 and >10 kg (22 lb). The Q-NRG & Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only (limited to ICUs for ventilated patients).	Measurement of resting metabolism (face mask): age 6 to adults; Measurement of resting metabolism (canopy dilution): 15 kg/30 lb to adults; Measurement of resting metabolism (ventilated patients): age 10 to adults.	Very similar. The subject device adds a lower limit for the patient's weight in order to avoid use of the device on people weighing less than 10 kg
Use environment	Indoor use (healthcare facilities)	Indoor use (healthcare facilities)	Same
Device measurements (output parameters)	Resting Energy Expenditure and related parameters (VO2, VCO2, RQ)	Resting Energy Expenditure and related parameters (VO2, VCO2, RQ) (other measurements available as options)	Same
Measurement mode(s)	Face mask, canopy, mechanically ventilated patients	Face mask, canopy, mechanically ventilated patients	Same
Measurement Range	Ventilation: 1-25 l/min VO2: 0.01-1 l/min VCO2: 0.01-1 l/min	Ventilation: 0-50 l/min VO2: not specified VCO2: not specified	Substantially equivalent for the maximum patient ventilation of the intended patient population and condition e.g. at rest.

Table 4: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Measurement Accuracy	Ventilation: <2% or 100 ml/min (whichever is greater) VO2: ±3% or 5 ml/min (whichever is greater) VCO2: ±3% or 5 ml/min (whichever is greater)	Ventilation: <3% VO2: ±3% VCO2: ±3%	Substantially equivalent
Major separate system components	• Q-NRG unit • Canopy hood & accessories • Optional PC software • Optional "Face Mask Mode" accessories • Optional ventilation mode accessories • Optional calibration accessories • Optional cart	• Quark RMR unit • Canopy hood & accessories • PC software • Optional "Face Mask Mode" accessories • Optional calibration accessories • Optional cart	Same
Flowmeter technology	Face mask: 18mm turbine flowmeter	Face mask: 18mm turbine flowmeter	Same
	Canopy: 18mm turbine flowmeter	Canopy: 18mm turbine flowmeter	
	Ventilator mode: disposable variable orifice pneumotach	Ventilator mode: disposable variable orifice pneumotach	
O2 sensor technology	Electrochemical	Paramagnetic	Substantially equivalent technology, the O2 electrochemical sensor is already used in K162515 and K071533
CO2 sensor technology	Infrared	Infrared	Same
Sampling technology	Internal mixing chamber	Breath by breath	Substantially equivalent technology, internal mixing chamber technology is already used in K162515 and K071533
User interface	Touch screen (unit) or keyboard and mouse (PC)	Keyboard and mouse (PC)	Similar. Subject device is designed to be mainly operated as a stand-alone unit
PC Software	Windows based application	Windows based application	Same
Biocompatibility	All direct patient contact and gas pathway components are biocompatible or used in already legally marketed devices with the same intended use	All direct and indirect patient contact components are biocompatible	Same
Sterility	Non-sterile	Non-sterile	Same
Anatomical sites	Indirect contact with patient's airways	Indirect contact with patient's airways	Same
Energy used	External or internal power supply	External power supply	Similar. Subject device can also be powered by an internal Li-Ion battery
Energy delivered	No energy delivered to patient	No energy delivered to patient	Same
Safety Standard:	ANSI/AAMI ES 60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012: class I / Internal power source, type BF applied part	IEC 60601-1: class I, type BF applied part	Similar. Subject device can be also powered by an internal Li-Ion battery
Dimensions	31 x 21 x 27 cm	17 x 30 x 45 cm	Differences have no effect on safety or effectiveness
Weight	4.65 kg	8 kg	Differences have no effect on safety or effectiveness

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:

- Device description
- Indications for use
- O2 sensor technology
- Sampling technology
- User interface
- Dimensions and weight
- Power supply

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

Conclusion

The subject and predicate devices have very similar intended uses and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.