June 23, 2023

Virtus Technology ApS
Leif Olesen
CTO
Svalevej 4
Roennede, DK-4683
Denmark

Re: K222982
Trade/Device Name: Virtus Metabolic Monitor
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY, BZL
Dated: May 15, 2023
Received: May 18, 2023

Dear Leif Olesen:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222982

Device Name
Virtus Metabolic Monitor

Indications for Use *(Describe)*

The Virtus Metabolic Monitor is indicated for the measurement of Resting Energy Expenditure (REE) for mechanically ventilated patients, who are non-spontaneous breathing, and who are at least 18 years of age.

The Virtus Metabolic Monitor is intended to be used in Intensive Care Units (ICUs) in professional healthcare facilities only.

The Virtus Metabolic Monitor is for prescription use only.

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) Summary in accordance with 21 CFR 807.92

Submitted by:	Virtus Technology Aps Svalevej 4 DK-4683 Roennede Denmark Tel.: +45 52 30 38 33 lo@virtusmonitor.com
Contact Person:	Mr. Leif Olesen
Position/Title:	CTO
Date of Preparation:	June 22, 2023

Trade Name:	Virtus Metabolic Monitor
Common/Classification Name:	Calculator, Predicted Values, Pulmonary Function and Computer, Oxygen-Uptake
Product Code(s):	21 CFR 868.1890, BTY and 21 CFR 868.1730, BZL
Class:	Class II

Predicate Device Substantial Equivalence to:

510(K) Number	Model	Manufacturer
K190800	Cosmed Q-NRG+ Portable Metabolic Monitor	Cosmed Srl Vi dei Piani di Monte Savello 37 Albano Laziale, 00041 Rome, Italy

Reference Devices:

Reference 1 K051092	GE Compact Airway Module, E-CAiOVX family	GE Healthcare 86 Pilgrim Road Needham, MA 02492 USA
Reference 2 K093080	TreyMed Metaphor Metabolic Monitor	TreyMed inc. N56 W24790 N. Corporate Cir., Unit C, Sussex, WI 53089, USA

Description of Device:

Virtus Metabolic Monitor is a metabolic monitors designed for the measurement of resting energy expenditure (REE) for mechanically ventilated adult patients in the Intensive Care Unit (ICU).

The device is enclosed in a metal casing with a color touch screen on front for user interaction and measurement results. On the left-hand side pneumatic connections to the flow and gas sensor (Flow Sensor) and on the rear the mains power inlet, on-switch, charging indicator and USB-connector for export of results.

The Virtus Metabolic Monitor is portable and is supplied from the built-in battery or from mains, where it is automatically charged.

Indications for Use:

The Virtus Metabolic Monitor is indicated for the measurement of Resting Energy Expenditure (REE) for mechanically ventilated patients, who are non-spontaneous breathing, and who are at least 18 years of age.

The Virtus Metabolic Monitor is intended to be used in Intensive Care Units (ICUs) in professional healthcare facilities only.

The Virtus Metabolic Monitor is for prescription use only.

Technological Characteristics:

The Virtus Metabolic Monitor utilizes the same technological principles as the predicate Cosmed Q-NRG+ device to continuously measure the oxygen uptake V'O2, carbon dioxide production V'CO2, and calculating the Resting Energy Expenditure REE and Respiratory Quotient RQ – both devices utilize the same control and gas sampling methods: microcontroller-driven control of gas analyzers using the side-stream method, calculation of parameters and presentation on a 10.1" color touch screen. The Virtus Metabolic Monitor uses a side-steam flow sensor and a gas sampling line for gas and flow sampling similar to the predicate device.

Comparison of Technological Features to Predicate and Reference Devices:

Product/Feature	Virtus Metabolic Monitor (Subject Device (SD))	Cosmed Q-NRG+ Portable Metabolic Monitor (predicate device(PD))	Remark
Manufacturer	Virtus Technology Aps	Cosmed Srl.	
Model Number	Virtus Metabolic Monitor VM-1	Cosmed Q-NRG+ Portable Metabolic Monitor	
510(k) Number	K222982	K190800	
Application/Intended use:	The Virtus Metabolic Monitor is indicated for the measurement of Resting Energy Expenditure (REE) for mechanically ventilated patients, who are non-spontaneous breathing, and who are at least 18 years of age.	The Q-NRG+ Portable Metabolic Monitor is indicated for the measurement of Resting Energy Expenditure (REE) for spontaneously breathing and (Q-NRG+ only) ventilated patients: -	Similar The SD is intended for patients, who are at least 18 years of age only, therefore the weight limitations are not applicable for the SD.

Product/Feature	Virtus Metabolic Monitor (Subject Device (SD))	Cosmed Q-NRG+ Portable Metabolic Monitor (predicate device(PD))	Remark
Patient Population	The SD is only intended for mechanically ventilated patients, who are non-spontaneous breathing.	- 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).	Similar Subject device claims for mechanically ventilated patients, who are non-spontaneous breathing, and who are at least 18 years of age is within the claims of the PD
Environment of Use	The Virtus Metabolic Monitor is intended to be used in Intensive Care Units (ICUs) in professional healthcare facilities only.	The device is intended to be used in professional healthcare facilities only (limited to ICUs for ventilated patients).	Same
Operation and Operating Principles			
Flow sensor	Fixed orifice pneumotach, which does not require calibration.	Variable orifice flow Pneumotach Flowmeter, which requires calibration before use.	Similar function to predicate device Same (identical) as used in RD2
CO2 Analyzer technology	Side stream infra-red	Side stream infra-red	Same
O2 Analyzer technology	Paramagnetic	Galvanic fuel cell	Similar / Substantially equivalent technology. Same technology as RD2
Flow Analyzer technology	Differential pressure signal	Differential pressure signal	Same
Placement of sensor	In breathing circuit between the endotracheal tube and filter and the ventilator circuit Y piece	In breathing circuit between the endotracheal tube and filter and the ventilator circuit Y piece	Same
Control Mechanism	Embedded microcontroller	Embedded microcontroller	Same
Modes of Operation	Ventilator mode	Ventilator, canopy, and mask modes	Similar The functionality of the ventilator mode is the same for the SD and the PD.

Product/Feature	Virtus Metabolic Monitor (Subject Device (SD))	Cosmed Q-NRG+ Portable Metabolic Monitor (predicate device(PD))	Remark
Operating Modes/Sequences	• Start device - power on • Select New Measurement • Enter Patient demographic • Attach Flow Sensor tubes • Connect Flow Sensor to patient airway tube • Start measurement • Review Result • Disconnect Flow Sensor from patient airway tube • Clean after use	• Start device - power on • Select New Measurement • Enter Patient demographic • *Select Ventilator mode* • *Calibrate flow sensor* • Attach Flow Sensor tubes • Connect Flow Sensor to patient airway tube • Start measurement • Review Result • Disconnect Flow Sensor from patient airway tube • Clean after use	Similar Calibration shall not be performed for the subject device and the simpler sequence and logic operation enhances the use of the subject device and therefore the sequence and logic operation are the same.
Measurement range and accuracy	Primary output parameters: REE: 500 – 7200 kcal/day ±3% RQ: 0.05 – 2 ±5% V'O2: 75-1000mL/min ±3% V'CO2: 75-1000mL/min ±3%	Primary output parameters: REE: 0-7200 kcal/day ±3% or 36kcal/day (whichever is greater) RQ: 0-2.00 ±5% or 0.04 (whichever is greater) V'O2: 0.01-1 L/min ±3% or 5mL/min (whichever is greater) V'CO2: 0.01-1L/min ±3% or 5mL/min (whichever is greater)	Primary output parameters are the same for SD and PD
Algorithms	Weir formula to calculate the Resting Energy Expenditure (REE)	Weir formula to calculate the Resting Energy Expenditure (REE)	Same
User Interface			
Display Type	Color TFT with integrated touchscreen	Color TFT with integrated touchscreen	Same
Navigation	Soft keys with symbols and clear text	Soft keys with symbols and clear text	Same

Product/Feature	Virtus Metabolic Monitor (Subject Device (SD))	Cosmed Q-NRG+ Portable Metabolic Monitor (predicate device(PD))	Remark
Output values	Measurements are shown in graphs and values for: Resting Energy Expenditure REE, Respiratory Quotient RQ, Oxygen uptake V'O2 & Carbon Dioxide production V'CO2	Measurements are shown in graphs and values for: Resting Energy Expenditure REE, Respiratory Quotient RQ, Oxygen uptake V'O2 & Carbon Dioxide production V'CO2	Same
Reports	Reports in .pdf and .csv formats exported to USB flash drive	Reports in .pdf and .csv formats exported to USB flash drive	Same
Power			
Power source: Mains	100-240VAC, 50/60Hz 50VA Class II double insulated	100-240VAC, 50/60Hz, 100-130VA Class I with protective earth	Similar Differences have no effect on safety or effectiveness
Internal Battery	Li-Ion "smart" battery, RRC2450, 3450mAh, 14.4V 49.7Wh Up to 3 hours operation	Li-Ion "smart" battery, RRC2450, 3450mAh, 14.4V 49.7Wh Up to 3 hours operation	Same
Rate of Protection	IPX0	IPX0	Same
Mechanical			
Dimensions	26 x 19.5 x 15 cm	31 x 21 x 27 cm	Similar size
Weight	2.5 kg	4.65	Similar weight
Mounting Options	Vesa 100	Vesa 100	Same

As summarized above, the Virtus Metabolic Monitor utilizes equivalent technological characteristics and specifications as the cleared predicate device.

Non-Clinical Tests:

The Virtus Metabolic Monitor was laboratory tested to current applicable standards for medical device electrical safety and electromagnetic compatibility. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1:2005+AMD1:2012
- Electromagnetic compatibility testing per IEC 60601-1-2:2014+A1:2020

The device met acceptance criteria for compliance to the standards.

Risk management, risk and hazard analysis was performed to the following standard:

- Application of risk management to medical devices per ISO 14971:2019
- Usability evaluation per IEC 62366-1:2015+A1:2020 for professional use

The device met risk management criteria for acceptability of residual risks.

The Virtus Metabolic Monitor embedded software was developed in accordance with FDA guidelines for moderate level of concern devices. The software lifecycle process was evaluated to meet:

- Medical device software lifecycle process per IEC 62304:2006+A1:2015 as per internal SW development QMS-procedure under ISO13485:2016
- Device software was verified to requirements and validated to meet the specified intended use.

The disposable Virtus Flow Sensor in its final finished form is identical to the EZ-Flow Sensor cleared in K093080. A materials certification was provided by TreyMed Inc to support this.

The disposable Virtus Flow Sensor met acceptance criteria for biocompatibility.

The Virtus Metabolic Monitor was evaluated for one year shelf-life and five years expected lifetime and met acceptance criteria for performance after testing.

The Virtus Metabolic Monitor was evaluated for usability and met acceptance criteria for performance after testing.

The Virtus Metabolic Monitor was tested side-by-side against the predicate device with respect to measure the oxygen uptake V'O2, carbon dioxide production V'CO2 and Resting Energy Expenditure REE. The test showed acceptable agreement of measurements between the subject device and the predicate device over the entire range from 100 – 1000 ml/min for both V'O2 and V'CO2 and hence the REE are equally close. It further showed that the subject device is capable of measuring V'O2 and V'CO2 up to 1000 ml/min and calculating the corresponding value of 7200kcal/day for REE. The side-by-side test met acceptance criteria for measurement comparison and accuracy.

In summary, the Virtus Metabolic Monitor met acceptance criteria for conformance to applicable standards, performance, biocompatibility and lifetime. Residual risks met criteria for acceptability for the intended use.

Conclusions: The Virtus Metabolic Monitor is substantially equivalent to the predicate device.