April 12, 2022

Covidien llc
Inna Reznikov
Regulatory Affairs Specialist
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K213518
Trade/Device Name: CARESCAPE CO2 Microstream parameter
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 7, 2022
Received: March 9, 2022

Dear Inna Reznikov:

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,

Todd Courtney
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213518

Device Name
CARESCAPE™* CO2 - Microstream™ parameter

Indications for Use *(Describe)*

The CARESCAPE™* CO2 - Microstream™ parameter, when connected to the host monitor, is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide (CO2) during the respiration cycle, EtCO2, FiCO2, and CO2 based respiration rate for adult, pediatric and neonatal patients, utilizing Microstream™ Advance CO2 sampling lines.
The CARESCAPE™* CO2 - Microstream™ parameter is intended for use in hospitals, hospital-type facilities, during intra-hospital transport between and within areas of care.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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CARESCAPE™* CO2 - Microstream™ parameter

510(k) Summary

The of 510(k) summary for the CARESCAPE™* CO2 - Microstream™ parameter is submitted in accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with the requirements of 21 CFR §807.92.

SUBMITTER INFORMATION

Submitted By:

Covidien, llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Date Prepared: October 31, 2021

Contact Person:

Inna Reznikov

Regulatory Affairs Specialist

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DEVICE

Trade Name:	CARESCAPE™* CO2 - Microstream™ parameter
Common Name:	Capnography - NanoPod
Classification Regulation:	21 CFR 868.1400
Classification Name:	Carbon Dioxide Gas Analyzer
Regulatory Class:	Class II
Product Code:	CCK
Review Panel:	Anesthesiology

PREDICATE DEVICE

Predicate Manufacturer:	Oridion Medical 1987 LTD
Predicate Trade Name:	Capnostream™35 Portable Respiratory Monitor
Predicate 510(k):	K150272

DEVICE DESCRIPTION

The GE CARESCAPE™* CO_2 -Microstream™ parameter is a module utilizing Microstream™ Capnography technology designed for use with specific GE Host monitors (CARESCAPE™* ONE, CARESCAPE™* B450 [K213234], CARESCAPE™* B650 [K213181], or CARESCAPE™* B850 [K213336]).

The GE CARESCAPE™* CO2 -Microstream™ parameter comprised of two main sub-systems:

- Microstream™ NanoMediCO2 is a Capnography module in its plastic enclosure called the NanoPod, responsible for measuring the inspired/expired carbon dioxide and respiration rate of adults, pediatric patients, and neonatal patients.

- U-MCO2-active cable module in its enclosure (called "Active cable" or "Bridge" or "Common block") responsible for enabling the bidirectional communication between the Host monitor and the NanoMediCo2 module, using the specific GE communication protocol (Tag-Length-Data). The Active Cable also acts as a power supply to the NanoPod, transferring power from the host to the pod and provides the user with an indication of the Pod's functional status.

The NanoPod mates on one side with the Microstream™ Advance Filter Lines. On the other side the NanoPod attaches to GE patient monitoring system via the U-MCO2- active cable, allowing them to display the Microstream™ Capnography parameters.

The U-MCO2 active cable module, is connected to an interface board located inside the active device (NanoPod), while on the other side of the U-MCO2 active cable, there is a proprietary GE (Amphenol) connector, designed to connect solely with GE Healthcare monitors. The NanoPod is activated by Microstream™ Advance Filter Lines that are connected through the blue door located on the upper side of the NanoPod.

INDICATIONS FOR USE

The CARESCAPE™* CO2 - Microstream™ parameter, when connected to the host monitor, is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide (CO2) during the respiration cycle, EtCO2, FiCO2, and CO2 based respiration rate for adult, pediatric and neonatal patients, utilizing Microstream™ Advance CO2 sampling lines. The CARESCAPE™* CO2 - Microstream™ parameter is intended for use in hospitals, hospital-type facilities, during intra-hospital transport between and within areas of care.

Note *(this statement is not part of the Indications for use)*: The indications for use of the subject device are a subset of (narrower than and encompassed by) the predicate device's indications and therefore fall within the same indications for use as that of the predicate. Thus, the indications for use statement of subject device are substantially equivalent to the indications for use of the predicate.

PRINCIPLE OF OPERATION

The NanoMediCO2, similarly to the MicroMediCO2 in the predicate Capnostream™35 Portable Respiratory Monitor (cleared by K150272), is an electrical board that is responsible for measuring the CO2 level by using non-dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO2 during every breath, the amount of CO2 present at the end of exhalation (etCO2), and the Respiratory Rate. Infrared spectroscopy is used to measure the

concentration of molecules that absorb infrared light. Because the absorption is proportional to the concentration of the absorbing molecule, the concentration can be determined by comparing its absorption to that of a known standard, ISO 80601-2-55. Once inside the Microstream™ CO2 sensor, the gas sample goes through a micro-sample cell (15 microliters). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO2 readings, even at high respiration rates.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The main difference between the subject of this submission to the predicate, is that the CARESCAPE™* CO_2 -Microstream™ parameter is an external single parameter, capnography module (CCK), designed to be connected to the GE host Monitor, while the predicate Capnostream™35 Portable Respiratory Monitor, is a standalone, dual parameter monitor, equipped with MicroMediCO2 capnography module (CCK) and a Nellcore pulse oximetry module (DQA).

The subject device, the CARESCAPE™* CO2 - Microstream™ parameter, has the same intended population, principle of operation, and fundamental technology as the capnography portion in the predicate device, the Capnostream™35 Portable Respiratory Monitor (K150272). The subject device is a derivative of the capnography module inside the predicate device with software and hardware modifications performed to enable the subject device to be used in conjunction with specific host monitors of GE (CARESCAPE™* ONE, CARESCAPE™* B450, CARESCAPE™* B650, or CARESCAPE™* B850

The verification and validation tests enable the use of the CARESCAPE™* CO2 - Microstream™ parameter for use with specific host monitors of GE (CARESCAPE™* ONE with software version 3.2, CARESCAPE™* B450, CARESCAPE™* B650, or CARESCAPE™* B850 with software version 3.2.). The subject device is intended to be used with the same Microstream™ Advance Filter Lines that are commercially available for use with the predicate device.

Based on the results of the verification and validation studies (including system verification), Covidien has established that the subject device, the CARESCAPE™* CO2 - Microstream™ parameter, is substantially equivalent to the predicate device.

The following technological characteristics were compared between the subject device and predicate device to demonstrate substantial equivalence in Table 1 below:

Table 1. Comparison of Technological Characteristics

Characteristic	Subject Device	Predicate Device K150272
Classification	II	II
Device Classification Name	Carbon Dioxide Gas Analyzer	Carbon Dioxide Gas Analyzer
Product Code	CCK	CCK DQA MNR
Purpose and Function	Continuous non-invasive monitoring of expired and inspired CO2, EtCO2,	Continuous non-invasive monitoring of expired and inspired CO2, EtCO2,

	capnography derived respiration rate	capnography derived respiration rate, SpO2 and pulse rate
Energy Source	Powered by the host monitor	Power supply operating on AC (90-264VAC), 47 to 63 Hz); alternatively, on a rechargeable internal lithium-ion battery or on a removable lithium-ion battery.
Target population	Adult, pediatric, and neonatal patients	Adult, pediatric, and neonatal patients
Intended user	Professionally trained health care providers	Professionally trained health care providers
Where used	In hospitals, hospital-type facilities, during intra-hospital transport between and within areas of care.	In hospitals, hospital-type facilities, intra-hospital transport, out-of-hospital Emergency Medical Service applications that include ground and air transport.
Fundamental Technology	Non-dispersive infrared (NDIR) (CO_2) Spectroscopy and Plethysmography	Non-dispersive infrared (NDIR) (CO_2) Spectroscopy and Plethysmography
Performance Standards	ISO 80601-2-55	ISO 80601-2-55 ISO 80601-2-61
External Materials	Polyurethane Silicon Copolyester	Polyurethane Silicon Polyester Polyetherimide Polycarbonate TPE
Main Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 80601-2-49 (section 202.8.102, Figure 202.104)	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-49 IEC 60601-1-12 IEC 60601-1-6 IEC 60601-1-8

MATERIALS

Each part of the product is made of a material that suits its functionality, the materials of the parts in the two products, the subject device, and the predicate, are not necessarily the same but are made up of identical material families, like plastics, metals, elastomers and others. Please refer to Table 1 for the external material comparison.

WHEN THE DEVICE IS USED AS INTENDED THERE IS NO DIRECT PATIENT CONTACT. External materials in the subject device comply to Biocompatibility standard ISO 10993.

PERFORMANCE DATA

The following performance data were provided to support the substantial equivalence determination with the predicate device.

Bench Performance Testing

The subject device, the CARESCAPE™* CO2 - Microstream™ parameter, is substantially equivalent to the predicate device, the Capnostream™35 (Portable Respiratory Monitor).

The functional features and the indications for use of the CARESCAPE™* CO2 - Microstream™ parameter are substantially equivalent to the predicate device.

The CARESCAPE™* CO2 - Microstream™ parameter has successfully undergone performance, safety, electromagnetic and environmental testing to ensure compliance with expected performance standards.

Software testing was performed to validate the performance of the CARESCAPE™* CO2 - Microstream™ parameter and its substantial equivalence to the predicate device.

A hazard analysis was carried out on the CARESCAPE™* CO2 - Microstream™ parameter in compliance with ISO 14971:2012. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the device.

Animal Performance Testing

Not applicable. Animal performance testing was not necessary to show substantial equivalence.

Clinical Performance Testing

Not applicable. Clinical evidence was not necessary to show substantial equivalence.

CONCLUSION

The subject device, CARESCAPE™* CO2 - Microstream™ parameter is similar in intended use, principle of operation, materials, technological characteristics and performance to the existing legally marketed device. The subject device, CARESCAPE™* CO2 - Microstream™ parameter, software and hardware modifications were made to maintain the intended performance of the subject device and to enable interface with specific GE Host monitors (CARESCAPE™* ONE, CARESCAPE™* B450 [K213234], CARESCAPE™* B650 [K213181], or CARESCAPE™* B850 [K213336]).

From the evidence presented in this Premarket Notification, the subject device can be considered substantially equivalent to the predicate device.