July 29, 2022

Covidien LLC
Andrew Berkeland
Senior Regulatory Affairs Specialist
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K213911
Trade/Device Name: Microstream CO2 NanoPod
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, BZQ
Dated: June 27, 2022
Received: June 28, 2022

Dear Andrew Berkeland:

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)*
K213911

Device Name
Microstream™ CO2 NanoPod

Indications for Use *(Describe)*
The Microstream™ CO2 NanoPod, when connected to the host monitor, is intended to provide 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™ and Microstream™ Advance CO2 sampling lines.
The Microstream™ CO2 NanoPod also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up.
IPI and ODI values can be calculated and displayed only if the host monitor collects SpO2 data and provides this SPO2 data to the NanoPod in order to calculate these parameters.
The Microstream™ CO2 NanoPod is intended for use in hospitals, hospital-type facilities, during intra-hospital transport between and within areas of care.

Contraindications:
The device is not to be used as an apnea monitor.

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.

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Microstream™ CO_2 NanoPod
510(k) Summary

This summary of 510(k) safety and effectiveness information for the Microstream™ CO_2 NanoPod 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: December 14, 2021

Primary Contact Person:
Andrew Berkeland
Senior Regulatory Affairs Specialist

Phone: (720) 501-7884
Email: andy.j.berkeland@medtronic.com

Secondary Contact Person:
Greeshma Kayala
Senior Regulatory Affairs Manager

Phone: (303) 579-1718
Email: greeshma.kayala@medtronic.com

DEVICE

Trade Name:	Microstream™ CO_2 NanoPod
Classification Name:	Capnography - NanoPod
Regulation:	21 CFR 868.1400, 21 CRF 868.2377
Regulatory Class:	Class II
Product Code:	CCK, BZQ
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 subject device of this premarket 510(k) notification is referred to as the Microstream™ CO_2 NanoPod throughout this submission.

The Microstream™ CO_2 NanoPod is a finished medical device that when connected to a host monitor is intended to provide continuous, non-invasive measurement and monitoring of carbon dioxide (CO_2) during the respiration cycle, including End-tidal CO_2 ($EtCO_2$), Fractional Concentration of Inspired CO_2 ($FiCO_2$), and CO_2 based respiration rate, for adult, pediatric, and neonatal patients utilizing Microstream™CO_2 or Microstream™ Advance CO_2 sampling lines.

The Microstream™ CO_2 NanoPod also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr), and oxygen desaturation index (ODI) values. The IPI measurement is intended for use in pediatric and adult patients only, and A/hr and ODI measurements are intended for age 22 and up. Both IPI and ODI values can be calculated and displayed only if the host monitor collects SpO_2 data and provides this SpO_2 data to the NanoPod to calculate these parameters.

The Microstream™ CO_2 NanoPod encloses a NanoMediCO2 capnography module, which measures inspired/expired carbon dioxide and respiration rate. The NanoPod is powered by the host monitor on a DC supply.

The Microstream™ CO_2 NanoPod system includes the following sub-systems:

- NanoPod is the medical device enclosure that encloses the NanoMediCO_2 module. The NanoPod has a connected active cable that has a LEMO connector end, which connects to a host monitoring system.
- NanoMediCO_2 capnography module is enclosed in the NanoPod. The NanoMediCO_2 module measures inspired and expired carbon dioxide and respiration rate. The active cable is what provides bidirectional communication between the Host monitor and the NanoMediCO_2 module enclosed inside the NanoPod.
- Interface Board is enclosed inside NanoPod which consists of an LED exposed on the outside of the NanoPod to provide the functional status of the subject device to the user.
- Cradle is a plastic holder used to connect the NanoPod with a GCX clamp or other mounting solution, which can then be used to mount the NanoPod on a pole or bedrail. There are no sharp edges on the Microstream™ CO_2 NanoPod, which enables the medical device to be held in the hand at times when it is removed from its mounting cradle.

The Microstream™ and or Microstream™ Advance CO_2 sampling lines can attach to the NanoPod CO_2 port on the NanoPod enclosure. Microstream™ Capnography parameters are displayed the Microstream™ and or Microstream™ Advance CO_2 sampling line is connected to the NanoPod CO_2 Port and the Microstream™ CO_2 NanoPod is connected via LEMO connector to a host monitoring system. Please note that the Microstream™ and Microstream™ Advance sampling lines have been cleared in their own respective 510K submissions.

INTENDED USE / INDICATIONS FOR USE

The Microstream™CO_2 NanoPod, when connected to the host monitor, is intended to provide continuous, non-invasive measurement and monitoring of carbon dioxide (CO_2) during the

respiration cycle, $EtCO_2$, $FiCO_2$, and CO_2-based respiration rate for adult, pediatric and neonatal patients, utilizing Microstream™ and Microstream™ Advance CO_2 sampling lines.

The Microstream™ CO_2 NanoPod also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up.

IPI and ODI values can be calculated and displayed only if the host monitor collects SpO_2 data and provides this SpO_2 data to the NanoPod in order to calculate these parameters.

The Microstream™ CO_2 NanoPod is intended for use in hospitals, hospital-type facilities, during intra-hospital transport between and within areas of care.

CONTRAINDICATIONS
The device is not to be used as an apnea monitor.

TECHNOLOGICAL CHARACTERISTICS
The main difference between the subject device and the predicate, is the fact that the Microstream™ CO_2 NanoPod is an external single parameter, capnography module, designed to be connected to a host monitor. The predicate Capnostream™35 Portable Respiratory Monitor (K150272), is a standalone, dual parameter monitor, equipped with MicroMediCO_2 capnography module (product code CCK) and a pulse oximetry module (product code DQA).

The subject device, the Microstream™ CO_2 NanoPod, has the same intended population, principles of operation, and fundamental technology as the predicate device, the Capnostream™35 Portable Respiratory Monitor. The subject device is a derivative of the capnography module that is inside the predicate device with software and hardware modifications to enable the subject device to be used in conjunction with an Original Equipment Manufacturer (OEM) host monitor.

Based on the results of the verification and validation studies, Covidien has established that the subject device, the Microstream™ CO_2 NanoPod, is substantially equivalent to the predicate device.

The following technological characteristics were compared between the subject device and the predicate device to demonstrate substantial equivalence.

Table 1. Comparison of Technological Characteristics

Characteristic	Subject Device	Predicate Device K150272
Classification	II	II
Device Classification Name	Carbon Dioxide Gas Analyzer and Breathing Frequency Monitor	Carbon Dioxide Gas Analyzer and Breathing Frequency Monitor
Product Code	CCK, BZQ	CCK DQA MNR
Purpose and Function	Continuous non-invasive monitoring of expired and inspired CO_2, $EtCO_2$,	Continuous non-invasive monitoring of expired and inspired CO_2, $EtCO_2$,

Characteristic	Subject Device	Predicate Device K150272
	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
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

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 Microstream™ CO_2 NanoPod, is substantially equivalent to the predicate device, the Capnostream™35 (Portable Respiratory Monitor).

The functional features and the intended use and indications for use of the Microstream™ CO_2 NanoPod are substantially equivalent to the predicate device.

The Microstream™ CO_2 NanoPod 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 Microstream™ CO_2 NanoPod and its substantial equivalence to the predicate device.

A hazard analysis was carried out on the Microstream™ CO_2 NanoPod in compliance with ISO 14971:2019. 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. No animal performance testing was required to demonstrate device safety and effectiveness.

Clinical Performance Testing
Not Applicable. No clinical performance testing was required to demonstrate device safety and effectiveness.

CONCLUSIONS
The subject device, Microstream™ CO_2 NanoPod is equivalent in intended use, technological characteristics, and performance to the existing legally marketed device. Testing did not raise any issue of safety and effectiveness; therefore, the device is substantially equivalent to the predicate device with respect to safety, effectiveness, indications for use and intended use.