April 5, 2023

Draegerwerk AG & Co. KGaA
Lyubov Lange
Regulatory Affairs Manager
53/55 Moislinger Allee
Luebeck, Schleswig-Holstein 23542
Germany

Re: K221118
Trade/Device Name: CO2 Mainstream Sensor
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 2, 2023
Received: March 6, 2023

Dear Lyubov Lange:

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 and Part 809); 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 -S

James J. Lee, Ph.D.
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)*
K221118

Device Name
CO2 Mainstream Sensor

Indications for Use *(Describe)*

Intended use

The Dräger CO2 Mainstream Sensor is a sensor for measuring the CO2 concentration in breathing gas (CO2 mainstream sensor).

Indications

The CO2 mainstream sensor enables the diagnosis and monitoring of patients by measuring CO2. The use of the medical device is limited to one patient at a time.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Premarket Notification Summary

Submitter: Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck, Germany
Establishment's registration number: 9611500

Contact Person: Dr. Bettina Moebius
Head of Regulatory Affairs Central
E-Mail: bettina.moebius@draeger.com
Telephone: +49 451 882 3247

Applicant's US Contact Person: Tom Hirte
Head of Regulatory Affairs
E-Mail: tom.hirte@draeger.com
Telephone: (978) 3796461

Date prepared: April 08, 2022

Device Name:

Trade Name:	CO2 Mainstream Sensor
Classification Name:	analyzer, gas, carbon-dioxide, gaseous-phase
Regulation Number:	21 CFR §868.1400
Product Code:	CCK
Class:	II

Predicate Device: INFINITY MCABLE - MAINSTREAM CO2, K100941

Drägerwerk AG & Co. KGaA is submitting a traditional 510(k) premarket notification for a new device, the CO2 Mainstream Sensor.

Device Description

The CO2 Mainstream Sensor is designed for continuous, non-invasive mainstream measurement of Carbon Dioxide. The sensor is able to monitor CO2 using an infrared absorption technique and measures end tidal CO2 and inspired CO2 and calculates the respiratory rate. The data are processed by a microcontroller and provided to the parent device via a serial interface.

The sensor is adapted to the breathing system by airway adapters (CO2 measuring cuvettes).

Intended Use

The Dräger CO2 Mainstream Sensor is a sensor for measuring the CO2 concentration in breathing gas (CO2 mainstream sensor).

Indications

The CO2 mainstream sensor enables the diagnosis and monitoring of patients by measuring CO2. The use of the medical device is limited to one patient at a time.

List of Consensus Standards

Standard Number and Version	Title
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC /TR 60601-4-2:2016	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-1-12:2014	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
ISO 80601-2-55:2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ANSI AAMI IEC 62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
AAMI / ANSI / IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
ANSI AAMI ISO 14971:2019	Medical devices - Applications of risk management to medical devices
ANSI AAMI ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Standard Number and Version	Title
ANSI AAMI ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

Comparison to Predicate

Specification	Proposed Device **CO2 Mainstream Sensor**	Predicate Device **INFINITY MCABLE – MAINSTREAM CO2**	Comments
Manufacturer	Drägerwerk AG & Co. KGaA	Draeger Medical AG & Co. KG	Same
510(k) Number	--	K100941	--
Regulation Number	868.1400 -	868.1400 -	Same
Product Code	CCK	CCK	Same
Classification	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Same
Regulatory Class	II	II	Same
Intended Use	The Dräger CO2 Mainstream Sensor is a sensor for measuring the CO2 concentration in breathing gas (CO2 mainstream sensor).	Dräger Infinity MCable.Mainstream CO2 is a sensor for measuring the CO2 concentration in breathing gas (CO2 mainstream sensor).	Same
Indications	The CO2 mainstream sensor enables the diagnosis and monitoring of patients by measuring CO2. The use of the medical device is limited to one patient at a time.	-	Different Detailed information establishes better understanding for the user while function, use and patient population of the sensor in the clinical setting remain identical. The safety and effectiveness of the current design is supported by biocompatibility, software, electromagnetic compatibility, electrical safety and bench testing and is finally not affected and the Intended Use not altered.

Specification	Proposed Device **CO2 Mainstream Sensor**	Predicate Device **INFINITY MCABLE – MAINSTREAM CO2**	Comments
Target Population / Patient Population	Adult, Pediatric	From neonates to adults.	Same The patient population has not been changed from predicate. The terms "neonate" and “pediatric” have been defined more specifically in recent years.
Technological Characteristics			
Principle of Operation	Measurement based on the principle that CO2 molecules absorb light at a specific wavelength. Dual wavelength infrared absorption.	Measurement based on the principle that CO2 molecules absorb light at a specific wavelength. Dual wavelength infrared absorption.	Same
Physical Attributes			
Sensor head dimensions	~45 x 30 x 20 mm	~50 x 30 x 20 mm	Similar The new sensor head could be designed smaller thanks to a new photo detector. No effect on function
Protection against penetrating liquids in accordance with IEC 60529	IP64	IP64	Same
Environmental			
Operating Temperature	–20 to +50 °C (–4 to 122 °F)	See Instructions for Use of the parent device: K103625, –20 to +50 °C (–4 to 122 °F)	Same
Operating Humidity	5 to 95 %, non-condensing	See Instructions for Use of the parent device: K103625, 5 to 95 % (no condensation)	Same

Specification	Proposed Device **CO2 Mainstream Sensor**	Predicate Device **INFINITY MCABLE – MAINSTREAM CO2**	Comments
Operating Ambient Air Pressure	570 to 1100 hPa (428 to 825 mmHg)	57 - 110 kPa (K100941)	Same
Storage Temperature	–40 to 75 °C (–40 to 167 °F)	–40 to 75 °C (–40 to 167 °F)	Same
Storage Humidity	5 to 95 %, non-condensing	5 to 95 % (no condensation)	Same
Storage Ambient Air Pressure	115 to 1100 hPa (86 to 825 mmHg)	115 to 1100 hPa (1.67 to 15.95 psi)	Same
General Performance			
Measuring Principle	Infrared absorption spectroscopy	Infrared absorption spectroscopy	Same
Respiratory Rate Range	0 to 150 /min	0 to 150 /min	Same
Measuring range	0 to 15.8 Vol% (at 1013 hPa), 0 to 16.0 kPa, 0 to 120 mmHg	0 to 13.2 Vol.%, 0 to 13.3 kPa, 0 to 100 mmHg	Similar Specification for extended range 100 to 120 mmHg not published previously
External Communication			
Communication with host device	RS 232 interface	RS 232 interface	Similar No effect on communication.

Discussion of Non-clinical Testing

The CO2 Mainstream Sensor is a new device and has undergone extensive testing to qualify it with e.g. national and international consensus standards, technical system requirements and other requirements. The following identified verification and validation activities necessary to establish substantial equivalence to the predicate device were carried out under well-established methods, their results summarized in Test Summary tables and the evidence included in this submission.

- Sterilization
- Biocompatibility
- Software, including cybersecurity
- IEC 60601-1-6 *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
- IEC 62366-1 *Medical devices – Part 1: Application of usability engineering to medical devices*
- Human Factors engineering
- Electrical safety
- Electromagnetic compatibility (EMC)
- IEC 60601-1-12 *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
- ISO 80601-2-55 *Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
- Technical System Requirements, covering:
  - Risk control measures
  - Technical data
  - Essential safety and performance
- Accessories compatibility

Conclusion

The conclusions drawn from the non-clinical tests and the comparison of intended use and technological characteristics with its predicate demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device INFINITY MCABLE – MAINSTREAM CO2 (K100941) identified in this section.

- END -