March 29, 2021

Masimo Corporation
Katelynn Kirby
Regulatory Affairs Specialist III
52 Discovery
Irvine, California 92618

Re: K201590
Trade/Device Name: EMMA Capnograph
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: February 26, 2021
Received: March 2, 2021

Dear Katelynn Kirby:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201590

Device Name
EMMA Capnograph

Indications for Use *(Describe)*
EMMA® Capnograph measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant 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
K201590

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	June 11 2020
Contact:	Katelynn Kirby Regulatory Affairs Specialist III Masimo Corporation Phone: (949) 297-7408
Trade Name:	EMMA Capnograph
Common Name:	Carbon Dioxide Gas Analyzer
Classification Regulation:	21 CFR 868.1400, Class II
Product Code:	CCK
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Addition of Wireless Capabilities
Predicate Device:	K072813 – EMMA Emergency Capnometer
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

5.1. Device Description

The subject device, EMMA® Capnograph (EMMA), the same as the predicate, is a portable medical device capable of measuring, displaying, and monitoring carbon dioxide and respiratory rates from exhaled air. The difference between the subject device and the predicate device is the addition of the wireless capability to allow for the wireless transmission of data. The intended use and measurement functions have not changed from the previous clearance.

The specifications for EMMA are as follows:

Feature	EMMA Specification
General	
Display type	Integrated Visual Display
Airway Adapter Adult/Pediatric	Single patient use proprietary airway adapter, 6 cc dead space.
Airway Adapter Infant	Single patient use proprietary airway adapter, 1 cc dead space.
Performance Specifications	
CO2	0-40 mmHg: +/- 2 mmHg,

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Feature	EMMA Specification
	41-99 mmHg: 6% of reading
Respiration Rate (3-150 breaths/min)	± 1 breaths/min
Total System Response Time	< 0.7 s
Displays/ Indicators	
Data displayed	CO2, Respiration Rate
Alarm	No Breath Detected, No Adapter, Check Adapter, Low battery, Low / High $ETCO_2$ with adjustable alarm limits.
Electrical	
Internal battery power	2 “AAA” Batteries
Output Interface	
Wireless Output	Supports Bluetooth wireless communication
Mechanical	
Enclosure Material	Thermoplastic
Dimensions	52 x 39 x 39 mm (2.1 x 1.5 x 1.5 inches)
Weight	65 g (2.1 oz) with batteries
Environmental	
Operating Temperature	-5 to 50 °C (23 to 122 °F)
Storage/Transport Temperature	-40 to 70 °C (-40 to 158 °F)
Operating Humidity	10 - 95%, non-condensing
Storage/Transport Humidity	10 - 95%, non-condensing
Operating Atmospheric Pressure	60 - 120 kPa
Compliance	
Electrical Safety/EMC	IEC 60601 compliant
Type of Protection	Internally powered
Degree of Protection	Defibrillation proof, BF-applied part
Degree of Ingress Protection	IP44
Mode of Operation	Continuous operation
Wireless Specifications	
Type	Bluetooth GFSK
Frequency	2402-2480 MHz
Max Peak Output Power	-1 dBm
Antenna Peak Gain	-7 dBi
Recommended Range	~10 feet (~3 meters) line-of-sight

5.2. Intended Use/ Indications for Use

EMMA® Capnograph measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

5.3. Technological Characteristics

Principle of Operation

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The measurement of CO2 in the breathing gas mixture is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of invisible infrared light is directed through the respiratory gas flow in the EMMA Airway Adapter. As the beam passes through the airway adapter, some of the light is absorbed by the gas mixture. The amount of absorbed light is measured by a miniaturized two channel spectrometer positioned to receive the infrared light beam.

The spectrometer incorporates two different optical "color" filters. The wavelength ranges of these filters are chosen such that one filters out wavelengths where carbon dioxide has very strong absorption and the other filters out wavelengths where carbon dioxide has no absorption.

The spectrometer also incorporates an infrared detector that converts the light beam to an electrical signal. The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light measured through the two filters is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.

Mechanism of Action for Achieving the Intended Effect

The EMMA works by attaching the EMMA Airway adapter between the endotracheal tube and resuscitation bag. The EMMA Airway Adapter once connected to the EMMA monitor becomes the path in which the breathing gas mixture passes. As the breathing gas mixtures passes, the infrared light passes through the light window provided in the adapter. The light window of the adapter aligns on the side with the infrared source and the other side with infrared detector. Based upon the amount of light absorbed when the different filters are in place, a CO2 and respiration rate is displayed on the EMMA monitor.

The EMMA Capnograph snaps in place on top of the EMMA Airway Adapter. The airway adapter may then, for example, be inserted between the endotracheal tube and the resuscitation bag or between the resuscitation bag and the patient mask.

Respiratory gas measurements are, as described in the previous section, obtained by continuously measuring the infrared light absorption through the ”XTP Windows” that are transparent to light in the wavelength ranges of interest.

The Airway Adapters are fully sealed, except for the breathing circuit couplings. The breathing circuit couplings conform to existing standards for this type of couplings. The EMMA Sensor Body (reusable portion) does not come in contact with breathing circuit gases or the patient.

5.4. Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The subject device incorporates a wireless module and a software modification to enable the radio and support the wireless communication of measurement data from EMMA.

There is no change to the intended use as part of this modification.

5.4.1 Similarities and Differences between Predicate and Subject Device

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The subject device, EMMA with wireless capabilities, and the predicate device, have the following key similarities:

- Both devices have the same intended use;
- Both devices have the same indicated populations;
- Both devices have the same measurement technology;
- Both devices have the same form factor

The subject device, EMMA with wireless capabilities, and the predicate device, have the following key differences:

- Subject device includes the ability to wirelessly communicate
- Subject device has a lower storage/transport specification

The purpose of this submission is the addition of the wireless capabilities to the EMMA. As part of the wireless function implementation, a radio module was incorporated into the hardware design and the software was updated to enable the wireless communication. There was no change to the measurement functions or the intended use of the device.

To support the wireless capabilities do not raise different questions of safety and effectiveness, the subject device was evaluated for electromagnetic compatibility testing to the latest IEC 60601-1-2 standard, radio co-existence testing, and cybersecurity risk mitigations.

The testing conducted supported the subject device to be substantially equivalent to the predicate device. Both devices have the same intended use and that the addition of the wireless capabilities does not raise different questions of safety and effectiveness.

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Table 12.5 – Comparison Table			
Feature	**EMMA Capnograph with wireless capabilities (Subject Device)**	**EMMA Emergency Capnometer (Predicate device)**	**Comparison**
510(k) Number	**Pending**	**K072813**	
General Information			
Classification	21 CFR 868.1400, Class II	21 CFR 868.1400, Class II	Same
Product Code	CCK	CCK	Same
Indications for Use	EMMA® Capnograph measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.	The EMMA Emergency Capnometer Monitor measures, displays and monitors carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.	Similar, carbon dioxide concentration clarified as carbon dioxide partial pressure.
Principle of Operation	The measurement of CO2 in the breathing gas mixture is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of invisible infrared light is directed through the respiratory gas flow in the EMMA Airway Adapter. As the beam passes through the airway adapter, some of the light is absorbed by the gas mixture. The amount of absorbed light is measured by a miniaturized two channel spectrometer positioned to receive the infrared light beam. The spectrometer incorporates two different optical "color" filters. The wavelength ranges of these filters are chosen such that one filters out wavelengths where carbon dioxide has very strong absorption and the other filters out wavelengths where carbon dioxide has no absorption. The spectrometer also incorporates an infrared detector that converts the light beam to an electrical signal. The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light measured	The measurement of CO2 in the breathing gas mixture is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of invisible infrared light is directed through the respiratory gas flow in the EMMA Airway Adapter. As the beam passes through the airway adapter, some of the light is absorbed by the gas mixture. The amount of absorbed light is measured by a miniaturized two channel spectrometer positioned to receive the infrared light beam. The spectrometer incorporates two different optical "color" filters. The wavelength ranges of these filters are chosen such that one filters out wavelengths where carbon dioxide has very strong absorption and the other filters out wavelengths where carbon dioxide has no absorption. The spectrometer also incorporates an infrared detector that converts the light beam to an electrical signal. The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light measured	Same

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	through the two filters is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.	through the two filters is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.	
Display			
Display type	Integrated visual display	Integrated visual display	Same
Airway Adapter Adult/Pediatric	Single patient use proprietary airway adapter, 6 cc dead space.	Single patient use proprietary airway adapter, 6 cc dead space.	Same
Airway Adapter Infant	Single patient use proprietary airway adapter, 1 cc dead space.	Single patient use proprietary airway adapter, 1 cc dead space.	Same
Technological Characteristics EMMA			
Display/Indicators			
Data displayed	CO2, Respiration Rate	CO2, Respiration Rate	Same
Alarm	No Breath Detected, No Adapter, Check Adapter, Low battery, Low / High $ETCO_2$ with adjustable alarm limits.	No Breath Detected, No Adapter, Check Adapter, Low battery, Low / High $ETCO_2$ with adjustable alarm limits.	Same
Accuracy			
CO2	0-40 mmHg: +/- 2 mmHg, 41-99 mmHg: 6% of reading	0-40 mmHg: +/- 2 mmHg, 41-99 mmHg: 6% of reading	Same
Respiration rate	3-150 breaths/min $\pm$ 1 breaths/min	3-150 breaths/min $\pm$ 1 breaths/min	Same
Environmental			
Operating Temperature	-5 to 50 °C (23 to 122 °F)	-5 to 50 °C (23 to 122 °F)	Same
Storage/Transport Temperature	-40 to 70 °C (-40 to 158 °F)	-30 to 70 °C (-22 to 158 °F)	Subject Device Storage/Transport Temperature Extended to -40 to 70 °C
Operating Humidity	10 - 95%, non-condensing	10 - 95%, non-condensing	Same
Storage/Transport Humidity	10 - 95%, non-condensing	5 - 100%, non-condensing	Subject Device Storage/Transport narrowed to 10 - 95%
Operating Atmospheric Pressure	60 - 120 kPa	70 - 120 kPa	Subject Device Operating Atmospheric Pressure extended to 60 -

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			120 kPa
Mechanical			
Enclosure Material	Thermoplastic	Thermoplastic	Same
Dimensions	52 x 39 x 39 mm (2.1 x 1.5 x 1.5 inches)	52 x 39 x 39 mm (2.1 x 1.5 x 1.5 inches)	Same
Weight	65 g (2.1 oz) with batteries	65 g (2.1 oz) with batteries	Same
Electrical			
Battery power	Internal battery power with 2 “AAA” Batteries	Internal battery power with 2 “AAA” Batteries	Same
I/O Interface			
Wireless	Bluetooth	None	Subject device is provided with additional Bluetooth wireless communication capabilities.
Mode of Operation			
Mode of operation	Continuous	Continuous	Same

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5.5. Summary of Design Control Activities

The hardware and software was modified to add the wireless capabilities to EMMA. See summary of Design Control Activities provided below.

Modification	Test Performed	Test Results
Hardware and software was modified to add wireless radio module	EMC Testing in accordance with IEC 60601-1-2:2014, including radiated immunity to 10 V/m.	Testing supports the addition of the wireless radio capabilities does not impact the essential performance.
	Radio co-existence testing in accordance with the FDA Guidance for Radio Frequency Wireless Technology in Medical Devices	Testing supports the quality of the service of the wireless connection is maintained under normal and anticipated abnormal conditions.
	Cybersecurity testing in accordance with the FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices	Testing supports the acceptability of the cybersecurity risks.
Storage and Transport Specification	Conducted operational verification after storage of the device at -40°C	Test supports the acceptability of the lower temperature specification
Operating Atmospheric Pressure	Conducted operational verification of the device at 60 kPa atmospheric pressure.	Test supports the acceptability of the lower temperature specification.

5.6 Conclusion

The data supports the substantial equivalence of the subject device, EMMA with wireless capabilities, to the predicate.