May 1, 2026

Covidien LLC.
Shannon Ryan
Senior Regulatory Affairs Specialist
200 Medtronic Dr
Lafayette, Colorado 80026

Re: K253030
Trade/Device Name: Capnostream™35 Portable Respiratory Monitor (PM35MN)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, DQA, MNR
Dated: April 3, 2026
Received: April 3, 2026

Dear Shannon Ryan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253030 ?

Please provide the device trade name(s). ?

Capnostream™ 35 Portable Respiratory Monitor (PM35MN)

Please provide your Indications for Use below. ?

The Capnostream ™ 35 monitor is a portable capnograph and pulse oximetry monitor indicated for non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath (EtCO2), respiration rate (RR), arterial oxygen saturation (SpO2), and pulse rate (PR) in patient populations, including adults, pediatrics, and neonates. The Capnostream ™ 35 monitor is indicated for use by professionally trained health care providers.

The Capnostream ™ 35 monitor is intended for use in hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport, unless otherwise noted. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and rotary-wing aircraft.

The Capnostream ™ 35 monitor with Microstream™ capnography and accessories is indicated for continuous non-invasive monitoring of capnography-derived respiratory rate, 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 adult patients only.

The Capnostream™ 35 monitor with Nellcor™ pulse oximeter and accessories are indicated for providing spot-check and/or continuous non-invasive monitoring of arterial oxygen saturation (SpO2), pulse rate (PR), pleth-derived respiratory rate, Saturation Pattern Detection (SPD), heart rate variability (HRV), and perfusion index (PI). It is intended for use with patients who are well- or poorly perfused, during both no-motion and motion conditions. The device is intended to maintain accuracy in monitoring conditions in which patient and/or pulse oximetry sensor characteristics may affect measurements, by leveraging patient-specific and sensor-specific information to aid in arterial oxygen saturation calculation.

The Saturation Pattern Detection™ Alert (SPD) parameter is intended to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs for continuous monitoring of adults in hospital, hospital-type facilities, and during intra-hospital transport only.

The Respiration Rate (RR) parameter, when used in conjunction with a NellcorTM Respiration Rate sensor, is intended to be used for spot-check or continuous monitoring of respiration rate in adults in hospital, hospital-type facilities, and during and intra-hospital transport only.

The Heart Rate Variability (HRV) is intended for continuous monitoring of the variability of a patient's pulse rate. The Heart Rate Variability is intended to analyze the pulse rate provided by the oximeter and provide visualization of trends in the pulse rate and HRV values.

The perfusion index is intended for spot-check or continuous monitoring of peripheral perfusion at the pulse oximetry sensor site and provides the ratio of the pulsatile blood to non-pulsatile or static blood in peripheral tissue.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information for the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ™ Intelligent Processor (Nell-EQ PCBA) 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.

I. SUBMITTER INFORMATION

Submitted By:	Covidien llc 200 Medtronic Dr Lafayette, CO 80026
Establishment Registration Number:	2936999
Contact Person:	Shannon Ryan, Senior Regulatory Affairs Specialist Phone: (303) 204-5241 Email: shannon.ryan2@medtronic.com
Secondary Contact:	Elli Bosek, Regulatory Affairs Manager Phone: (303) 408-0731 Email: elli.m.bosek@medtronic.com
Date:	April 30, 2026

II. DEVICE

Trade or Proprietary Name:	Capnostream™ 35 Portable Respiratory Monitor
Common Name:	Analyzer, gas, carbon-dioxide, gaseous-phase
Regulation Number:	21 CFR § 868.1400 21 CFR § 870.2700 21 CFR § 868.2375
Classification Name:	Carbon Dioxide Gas Analyzer Oximeter Breathing Frequency Monitor
Regulatory Class:	Class II

Product Code: CCK, DQA, MNR

Review Panel: Anesthesiology

III. PREDICATE & REFERENCE DEVICES

Predicate Device:

Predicate Manufacturer: Oridion Medical 1987 Ltd. (acquired by Covidien llc)
Predicate Device Name: Capnostream™ 35 Portable Respiratory Monitor
Predicate 510(k): K200594

IV. DEVICE DESCRIPTION

The Capnostream™ 35 is a portable, 4-inch color screen monitor designed for non-invasive monitoring of capnography and pulse oximetry. The device integrates two primary modules: the microMediCO$_2$ capnography module and the Nellcor™ Nell-EQ™ Intelligent Processor (PCBA). The Capnostream™ 35, functions as a host system, integrating outputs from these modules, displaying the associated parameters, and generating alarms when preset thresholds are exceeded.

The Capnostream™ 35 is intended for neonates, pediatrics and adults in hospitals, hospital-type facilities, intra-hospital transport, and mobile emergency medical applications, including both ground and air transport, unless otherwise noted. Transport environments include: intra-hospital transport and both ground and air emergency transport: road ambulances and rotary-wing aircraft.

The microMediCO$_2$ module provides the following parameters to the host system: end-tidal carbon dioxide (EtCO$_2$), respiration rate (RR), CO$_2$ waveform, integrated pulmonary index (IPI), apnea per hour (A/hr), and oxygen desaturation index (ODI).

The Nellcor™ Nell-EQ™ Intelligent Processor provides the following parameters to the host system: arterial oxygen saturation (SpO$_2$), pulse rate (PR), plethysmograph-derived respiratory rate (RR), saturation pattern detection (SPD), heart rate variability (HRV), and perfusion index (PI). The SpO$_2$ measurements are also provided to the microMediCO$_2$ module to support the calculation of integrated pulmonary index (IPI) and oxygen desaturation index (ODI).

V. INDICATIONS FOR USE

The Capnostream™ 35 monitor is a portable capnograph and pulse oximetry monitor indicated for non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath (EtCO$_2$), respiration rate (RR), arterial oxygen saturation (SpO$_2$), and pulse rate (PR) in patient populations, including adults, pediatrics, and neonates. The Capnostream™ 35 monitor is indicated for use by professionally trained health care providers. The Capnostream™ 35 monitor is intended for use in hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications

including both ground and air transport, unless otherwise noted. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and rotary-wing aircraft.

The Capnostream™ 35 monitor with Microstream™ capnography and accessories is indicated for continuous non-invasive monitoring of capnography-derived respiratory rate, 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 adult patients only.

The Capnostream™ 35 monitor with Nellcor™ pulse oximeter and accessories is indicated for providing spot-check and/or continuous non-invasive monitoring of arterial oxygen saturation (SpO_2), pulse rate (PR), pleth-derived respiratory rate, Saturation Pattern Detection (SPD), heart rate variability (HRV), and perfusion index (PI). It is intended for use with patients who are well- or poorly perfused, during both no-motion and motion conditions. The device is intended to maintain accuracy in monitoring conditions in which patient and/or pulse oximetry sensor characteristics may affect measurements, by leveraging patient-specific and sensor-specific information to aid in arterial oxygen saturation calculation.

The Saturation Pattern Detection™ Alert (SPD) parameter is intended to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs for continuous monitoring of adults in hospital, hospital-type facilities, during intra-hospital transport only.

The Respiration Rate (RR) parameter, when used in conjunction with a Nellcor™ Respiration Rate sensor, is intended to be used for spot-check or continuous monitoring of respiration rate in adults in hospital, hospital-type facilities, during intra-hospital transport only.

The Heart Rate Variability (HRV) is intended for continuous monitoring of the variability of a patient's pulse rate. The Heart Rate Variability is intended to analyze the pulse rate provided by the oximeter and provide visualization of trends in the pulse rate and HRV values.

The perfusion index is intended for spot- check or continuous monitoring of peripheral perfusion at the pulse oximetry sensor site and provides the ratio of the pulsatile blood to non-pulsatile or static blood in peripheral tissue.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device is substantially equivalent to the predicate device (K200594). Both devices share the same intended use, patient populations, and underlying monitoring technology characteristics; the subject device additionally incorporates the Nell-EQ™ intelligent processor, to provide expanded oximetry functionality. The following technological characteristics were compared between the subject and predicate devices to demonstrate substantial equivalence:

Device Characteristics	Subject Device	Predicate Device (K200594)	Comments
Classification	II	II	Same
Product Code	CCK DQA MNR	CCK DQA MNR	Same
Intended Use	Non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath ($EtCO_2$), respiration rate (RR) [from capnography], arterial oxygen saturation (SpO_2), and pulse rate (PR)	Non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath ($EtCO_2$), respiration rate (RR) [from capnography], arterial oxygen saturation (SpO_2), and pulse rate (PR)	Same
Patient Population	Neonatal, pediatric, and adult patients. A/hr and ODI are intended for adult patients only. IPI is intended for pediatric and adult patients only. SPD and RR are intended for adults only.	Neonatal, pediatric, and adult patients. A/hr and ODI indication for use is for adult patients age 22 and up. IPI is intended for pediatric and adult patients only. Indication for use of RR and SPD is for adult patients age 22 and up.	Same. Target populations are unchanged. Age-related phrasing clarified without altering indications.

Device Characteristics	Subject Device	Predicate Device (K200594)	Comments
Use Environment	In hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport, unless otherwise noted. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and rotary-wing aircraft. SPD and RR are for use in hospitals, hospital- type facilities, and during intra-hospital transport only.	In hospitals, hospital- type facilities, intra- hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport. SPD and RR are for use in hospitals and hospital- type facilities only.	Same. Use environments are unchanged; subject device language clarified to describe transport conditions more specifically.
Fundamental Technology	NDIR (CO_2) Spectrophotometry and Plethysmography	NDIR (CO_2) Spectrophotometry and Plethysmography	Same
Capnograph Module Integrated	microMediCO$_2$	microMediCO$_2$	Same
Capnograph Module Outputs	EtCO$_2$ numeric, Respiratory Rate, Integrated Pulmonary Index (IPI), Continuous CO$_2$ waveform, Apnea per Hour (A/hr), and Oxygen Desaturation Index (ODI)	EtCO$_2$ numeric, Respiratory Rate, Integrated Pulmonary Index (IPI), Continuous CO$_2$ waveform, Apnea per Hour (A/hr), and Oxygen Desaturation Index (ODI)	Same
Capnograph Specifications	**EtCO$_2$ Range**: 0-150mmHg **EtCO$_2$ Accuracy**: 0-38 ± 2 mmHg 39-150 ±5% mmHg of reading + 8% for every 1 mmHg above 38 mmHg **RR Range:** 0-150 bpm **RR Accuracy**: 0-70 bpm: ±1 bpm 71-120bpm: ±2 bpm 121-150 bpm: ± 3 bpm	**EtCO$_2$ Range**: 0-150mmHg **EtCO$_2$ Accuracy**: 0-38 ± 2 mmHg 39-150 ±5% mmHg of reading + 8% for every 1 mmHg above 38 mmHg **RR Range:** 0-150 bpm **RR Accuracy**: 0-70 bpm: ±1 bpm 71-120bpm: ±2 bpm 121-150 bpm: ± 3 bpm	Same

Device Characteristics	Subject Device	Predicate Device (K200594)	Comments
Pulse Oximeter Technology Integrated	Nell-EQ™ Intelligent Processor	PMB05N Printed Circuit Board Assembly (PCBA)	Substantially equivalent; Nell-EQ PCBA is the updated oximetry engine, with expanded parameters.
Pulse Oximeter Technology Outputs	SpO_2, pulse rate (PR), pleth-derived respiration rate (RR), saturation pattern detection (SPD), heart rate variability (HRV), perfusion index (PI)	SpO_2, pulse rate (PR), pleth-derived respiration rate (RR), saturation pattern detection (SPD)	Substantially equivalent; Subject device adds HRV and PI as supplemental displayed parameters. Safety and efficacy of the additional parameters have been verified through both bench and clinical testing to meet intended design requirements.
Pulse Oximeter Specification	**SpO_2 Display Range:** 1-100% **SpO_2 Accuracy**: Adult, Pediatric, Infant: 70-100% ±2 digits. Neonate: 70-100% ±2 digits. Adult, Pediatric, Neonate, Infant with Motion: 70- 100% ±3 digits. Low Perfusion: 70-100% ±2 digits. Low Saturation: 60-80% ±3 digits. **Pulse Rate Range**:20-250 bpm **Pulse Rate Accuracy**: Adult, Pediatric, Neonate, Infant: 20-250 bpm ±3 digits. Low Perfusion: 20-250 bpm ±3 digits. Adult, Pediatric, Neonate, Infant with Motion: 20-250 ±5 digits. **RR Range**: 4-40 bpm **RR Accuracy**: ±1 bpm (mean	**SpO_2 Display Range:** 1-100% **SpO_2 Accuracy**: Adult and Pediatric modes, without motion: 70-100% ±2 digits. Including under low perfusion. Infant/Neonatal mode, without motion: 70-100% ±2 digits. Adults and Pediatric mode, with motion: 70- 100% ±3 digits. Infant/Neonates mode- with motion: 70 – 100% ±3 digits. With low saturation 60-80% ±3 digits. **Pulse Rate Range**: No motion: 20-250 bpm With motion: 48-127 bpm **Pulse Rate Accuracy**:	Same, the overall pulse oximetry specifications have not changed from the predicate device with the integration of the Nell-EQ PCBA. SpO_2 and pulse rate accuracy specifications are consistent with the predicate device. These specifications were verified across bench, software, and clinical testing. Verification testing confirmed performance met or exceeded requirements. Perfusion Index and Heart Rate Variability are additional displayed parameters on the subject device.

Device Characteristics	Subject Device	Predicate Device (K200594)	Comments
	error) **Perfusion Index Range:** 0 – 25.5% **Heart Rate Variability Range:** 0 – 80 bpm	No motion: ±3 digits. With motion: ±5 digits. **RR Range**: 4-40 bpm **RR Accuracy**: ±1 bpm (mean error)	
Disparate Bias Disclosure/ Performance	Performance across diverse skin tones was evaluated using both the Monk Skin Tone (MST) scale and Individual Typology Angle (ITA) measurement. Disparate bias results are included in device labeling.	N/A – Disparate bias was not disclosed for the legacy pulse oximeter.	Subject device includes bias disclosure in subject device labeling. Clinical studies included representation across the full MST range. Testing confirmed that accuracy performance met or exceeded specifications across skin tone cohorts, including under motion, low-saturation, and low perfusion conditions. This disclosure represents the safety and effectiveness of the pulse oximetry technology verified via clinical testing.
Connectivity	No connectivity is available in subject device.	• LAN • WI-FI • Bluetooth • RS232 • SD card port • USB port	Substantially equivalent, software and hardware changes were completed on the subject device to irreversibly remove all connectivity options present in the predicate device. The intended use of this device does not depend on any connectivity, and hence is not impacted due to this change.

The subject Capnostream™ 35 Portable Respiratory Monitor and the predicate Capnostream™ 35 are substantially equivalent with respect to intended use, indications, core technologies, and overall

performance characteristics. Clarifications to the indications for use were made only to improve description and support the integration of the Nell-EQ™ Intelligent Processor (PCBA) into the host monitor. Integration of the Nell-EQ PCBA introduces advancements in oximetry performance including the addition of Heart Rate Variability (HRV) and Perfusion Index (PI) parameters. Verification and validation testing demonstrated that SpO_2 and pulse rate accuracy met or exceeded specifications under monitoring conditions such as motion and low perfusion.

These updates, together with comprehensive risk management activities, confirm that the technological differences introduced with Nell-EQ improve consistency and transparency in performance without raising new questions of safety or effectiveness. Therefore, the subject Capnostream™ 35 Portable Respiratory Monitor is substantially equivalent to the predicate device.

Technological Characteristics:

The primary technological difference between the predicate and subject Capnostream™ 35 monitors is the integration of the Nell-EQ™ Intelligent Processor (PCBA) as the updated pulse oximetry engine. The Nell-EQ PCBA represents the latest generation of Nellcor™ oximetry technology.

The Nell-EQ PCBA provides the host monitor with noninvasive measurements of arterial oxygen saturation (SpO_2) and pulse rate (PR), as well as derived parameters including plethysmograph-derived respiratory rate (RR) and Saturation Pattern Detection (SPD). Additional displayed parameters include heart rate variability (HRV) and perfusion index (PI), which offer supplemental context for assessing patient status.

Nell-EQ is designed to improve consistency of accuracy across patient populations and monitoring conditions, including motion, low perfusion, and varying sensor characteristics. Clinical testing incorporated evaluation across diverse skin tones using both the Monk Skin Tone (MST) scale and Individual Typology Angle (ITA), with results disclosed in subject device labeling.

The Nell-EQ introduces TrueSpectrum™ Calibration, which incorporates additional patient-specific optical inputs beyond the OxiMax™ DigiCal coefficients and raw signal ratios received from Nellcor™ sensors.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing – Bench:
In accordance with 21 CFR 807.87(g), bench performance testing was conducted on the subject device, the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ PCBA, to support a claim of substantial equivalence to the predicate device cleared in K200954 and to demonstrate that the device was designed to meet the design inputs. Verification and validation testing was completed at a system

level to ensure safety and effectiveness of the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ PCBA.

Non-clinical testing for the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ PCBA included the following:

- Performance
- Electrical Safety, EMC, Particular Standards
- Human Factors and Usability
- Reliability
- Software
- Hardware
- Mechanical
- Environmental
- Labeling
- Packaging

Additionally, testing illustrated the subject device complies with the following particular standards:

- ISO 80601-2-55, particular standard for capnography
- ISO 80601-2-61, particular standard for pulse oximetry
- ISO 80601-2-49, particular standard for multifunction patient monitors
- IEC 62133-2, battery safety

Biocompatibility Testing:
The subject device is not patient contacting and therefore biocompatibility testing is not applicable to this device.

Electrical Safety, EMC Testing:
Electrical safety and EMC testing were performed on the subject device. The subject device complies with 60601-1 standard for safety and 60601-1-2 standard for EMC.

Human Factors Evaluation:
A Human Factors assessment was conducted and the Capnostream™ 35 was found to be in conformance with EN 62366-1 and IEC 62366-1.

Software Testing:
Software verification and validation testing were conducted and provided as part of this submission as recommended by the FDA Guidance, "*Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*" (issued June 14, 2023) to support the software changes for the integration of the Nell-EQ PCBA into the Capnostream™ 35.

Performance Testing – Animal:
No animal performance testing was required to demonstrate subject device safety and effectiveness.

Performance Testing – Clinical:

Clinical study data were included as part of this submission to demonstrate the performance, safety, and effectiveness of the Nell-EQ PCBA, across skin pigmentation/skin tone sub-groups. The results supported the clinical performance of the subject device in accordance with ISO 80601-2-61. The subject device demonstrated SpO_2 accuracy within 2.0% A_{RMS}.

CONCLUSION

Based on the information provided in this premarket notification submission, including intended use, device comparisons and performance testing, the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ PCBA meets applicable safety and performance standards and perform as intended in a manner identical to the predicate. The different technological characteristics do not raise different questions of safety or effectiveness. Therefore, the Capnostream™ 35 Portable Respiratory Monitor with integrated Nell-EQ PCBA is considered substantially equivalent to the predicate device currently marketed for the same intended use.