April 27, 2020

Oridion Medical 1987 Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, DC, District of Columbia 20004

Re: K200594
Trade/Device Name: Capnostream 35 Portable Respiratory Monitor
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, DQA, MNR
Dated: March 6, 2020
Received: March 6, 2020

Dear Jonathan Kahan:

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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K200594

Device Name

Capnostream™35 Portable Respiratory Monitor

Indications for Use *(Describe)*

The Capnostream™35 monitor is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

The Capnostream™35 monitor 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. The OxiMax SPD™ alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

The Nellcor™ respiration rate parameter is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Other than the OxiMax SPD™ alert and Nellcor™ respiration rate features, the device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

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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K200594

510(k) SUMMARY

Oridion Medical 1987 Ltd.'s Capnostream™ 35 Portable Respiratory Monitor

Submitter

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Phone: +972-54-5449290Facsimile: +972-2-586-6680

Contact Person: Lital David

Date Prepared: April 17, 2020

Name of Device: Capnostream™ 35 Portable Respiratory Monitor

Common or Usual Name: Analyzer, gas, carbon-dioxide, gaseous-phase

Classification Name: 21 CFR 868.1400 Carbon dioxide gas analyzer
21 CFR 870.2700 Oximeter
21 CFR 868.2375 Breathing frequency monitor

Regulatory Class: II

Product Code: CCK, DQA, MNR

Predicate Devices

CapnoStream 35 Portable Respiratory Monitor (K150272)
NellCor Bedside Respiratory Patient Monitoring System (K141518)

Device Description

The Capnostream™35 is a 4-inch color screen portable two-parameter monitor consisting of a microMediCO2 capnography module and a pulse oximetry module implemented in a host device. The host device displays parameters received from the respective modules and generates alarms when preset alarm thresholds are crossed.

The microMediCO2 module provides the following inputs to the host monitor: EtCO2 numeric, Respiratory Rate, IPI (integrated Pulmonary Index), Continuous CO2 waveform, Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI).

The SpO2 module integrated in the Capnostream™35 monitor presented in this submission provides SpO2, Pulse Rate, Respiratory Rate, and saturation pattern detection (SPD) parameters to the host for display. The SpO2 measurements are also provided to the microMediCO2 module, enabling the calculation of IPI and ODI.

The host monitor will display this data to the user on a screen as numeric values, and will also display the CO2 waveform and SpO2 (pleth) waveform or pulse bar graph.

The device is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport as well as during out-of-hospital Emergency Medical Service applications. The device features IP54 Liquids & Solids ingress protection, 1.25M Shockproof status, sunlight readable display, automatic display brightness, hot swap battery capability and altitude use up to 15000 feet (4572m) for use in out-of-hospital Emergency Medical Service applications.

Indications for Use

The Capnostream™35 monitor is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

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The Nellcor™ respiration rate parameter is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities.

Other than the OxiMax SPD™ alert and Nellcor™ respiration rate features, the device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

Summary of Technological Characteristics

The primary difference between the subject and predicate devices is (1) addition of two pulse oximetry derived algorithms: Nellcor Respiratory Rate (RR) and Nellcor Saturation Pattern detection (SPD), (2) expansion of compatible WiFi authentication protocols, and (3) User Interface (GUI) language expansion. The sensor and algorithms used to sense RR and SPD are identical to K141518. There have been no changes to the hardware since clearance in K150272. Thus, these changes do not raise different questions of safety or efficacy.

Performance Data

Non-clinical tests were performed to support the determination of substantial equivalence:

- Software validation to ensure that all modified software functions as intended. This included cybersecurity documentation that identified cybersecurity risks and summarized how they were mitigated.
- Usability testing per IEC 60601-1-6. Testing assessed the ability of 15 intended users with varying levels of experience to perform key tasks as well as understand Capnostream™35's display.

- Wireless connectivity testing. The wireless communication testing passed for all wireless key types compatible with the device.

Conclusions

The modified Capnostream™35 is substantially equivalent to its predicate devices.