September 17, 2021

Covidien
Ashley Johnston
Regulatory Affairs Manager
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K203762
Trade/Device Name: Nellcor EASYCAP II Adult Colorimetric CO2 Detector, Nellcor PEDCICAP Pediatric Colorimetric CO2 Detector
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: August 19, 2021
Received: August 20, 2021

Dear Ashley Johnston:

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)*
K203762

Device Name
Nellcor™ EASYCAP II Adult Colorimetric CO2 Detector

Nellcor™ PEDICAP Pediatric Colorimetric CO2 Detector

Indications for Use *(Describe)*
Use to assist verification of tube placement during endotracheal or nasotracheal intubation.
Use on intubated patients to detect approximate ranges of end-tidal CO2 when clinically significant.

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."

COVIDIEN

510(k) SUMMARY
K203762

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the Nellcor™ EASYCAP II Colorimetric CO_2 Detector and Nellcor™ Pediatric Colorimetric CO_2 Detector.

I. SUBMITTER

Submitted By:	Covidien LLC 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	21 December 2020
Contact Person:	Ashley Johnston Regulatory Affairs Manager 720-440-1057

II. DEVICE

Proprietary Name:	Nellcor™ EASYCAP II Adult Colorimetric CO_2 Detector Nellcor™ PEDCICAP Pediatric Colorimetric CO_2 Detector
Common Name:	Carbon dioxide gas analyzer
Device Classification Regulation:	21 CFR 868.1400
Device Product Code & Panel:	CCK / Anesthesiology (73)
Class:	II

III. Predicate Device

Predicate Devices:	Pedi-CAP™ Pediatric End-Tidal CO_2 Detector (K944400)

IV. Device Description

The subject device, when connected between an endotracheal tube and a breathing device, detects approximate ranges of end-tidal CO_2 by color comparison in patients. The detector may be used during patient transport or in any location where intubations are performed. It may be used for up to 2 hours.

The subject device is non sterile and is intended for single use.

The EASYCAP II is used in adult patients weighing more than 15 kg (33 lb), and the PEDICAP is used in pediatric patients weighing 1 – 15 kg (2.2 – 33 lb).

V. Indications for Use/Intended Use

Use to assist verification of tube placement during endotracheal or nasotracheal intubation. Use on intubated patients to detect approximate ranges of end-tidal CO_2 when clinically significant.

VI. Technological Characteristics Comparison

The subject device has similar indications for use, design and functionality to the predicate device. A comparison table is provided below.

Device Comparison Table: Subject Device, Predicate Device

Features	Predicate Device	Subject Device Comparison	
	Nellcor Pedi-CAP™ Pediatric End-Tidal CO_2 Detector (K944400)	**Nellcor™ EASYCAP II Colorimetric CO_2 Detector**	**Nellcor™ PEDICAP Colorimetric CO_2 Detector**
Intended Use	To detect approximate ranges of end-tidal CO_2	Same as predicate	Same as predicate
Indications for Use	Intended for use during endotracheal or nasotracheal intubation to assist verification of tube placement. It is also intended for use on intubated patients where measuring approximate ranges of end-tidal CO_2 may be clinically significant and other more precise methods are not feasible or available.	Similar Use to assist verification of tube placement during endotracheal or nasotracheal intubation. Use on intubated patients to detect approximate ranges of end-tidal CO_2 when clinically significant.	Similar Use to assist verification of tube placement during endotracheal or nasotracheal intubation. Use on intubated patients to detect approximate ranges of end-tidal CO_2 when clinically significant.
Patient Population	Patients weighing 1–15 kg (2.2–33 lb).	Different Patients weighing more than 15 kg (33 lb). Justification for difference: The subject is used for adult patients.	Same as predicate
Use	Single patient	Same as predicate	Same as predicate

Device Comparison Table: Subject Device, Predicate Device

Features	Predicate Device	Subject Device Comparison	
	Nellcor Pedi-CAP™ Pediatric End-Tidal CO_2 Detector (K944400)	Nellcor™ EASYCAP II Colorimetric CO_2 Detector	Nellcor™ PEDICAP Colorimetric CO_2 Detector
Duration of Use	<2 hours	Same as predicate	Same as predicate
Features, Specification and Performance			
Sterilization	Non-sterile	Same as predicate	Same as predicate
Shelf Life	22 Months	Different 26 Months Justification for difference: The subject device was validated for longer shelf life.	Different 26 Months Justification for difference: The subject device was validated for longer shelf life.
Standard 15 mm connections	Yes	Same as predicate	Same as predicate
Dead Space (Volume)	3cc	Different 22cc Justification for difference: The subject device is intended for adult patient, therefore has different dead space in comparison to the predicate device. The difference in the dead space (volume) does not impact the safety and effectiveness of the device.	Same as predicate

Device Comparison Table: Subject Device, Predicate Device

Features	Predicate Device	Subject Device Comparison	
	Nellcor Pedi-CAP™ Pediatric End-Tidal CO_2 Detector (K944400)	**Nellcor™ EASYCAP II Colorimetric CO_2 Detector**	**Nellcor™ PEDICAP Colorimetric CO_2 Detector**
Resistance to Flow	2.5 cm H_2O ± 0.5 cm at 10L/min	Different 4.4 cm H_2O ± 1.0 cm at 60 L/min Justification for difference: The subject device is intended for adult patient, therefore has different resistance to flow in comparison to the predicate device. The difference in the resistance to flow does not impact the safety and effectiveness of the device.	Same as predicate
Detected % CO_2 Ranges and Colors	A: 0.03 < 0.5 % B: 0.05 < 2 % C: 2 – 5 %	Same as predicate	Same as predicate
Materials			
Device Cover	Acrylic copolymer	Same as predicate	Same as predicate
pH Indicator Paper	pH-sensitive indicator paper	Same as predicate	Same as predicate
Device Support	Polypropylene	Same as predicate	Same as predicate

COVIDIEN LLC
15 HAMPSHIRE STREET
MANSFIELD, MA 02048

508-261-8000 [T]

Device Comparison Table: Subject Device, Predicate Device

Features	Predicate Device	Subject Device Comparison	
	Nellcor Pedi-CAP™ Pediatric End-Tidal CO_2 Detector (K944400)	Nellcor™ EASYCAP II Colorimetric CO_2 Detector	Nellcor™ PEDICAP Colorimetric CO_2 Detector
Filter	Polypropylene	Different Polypropylene and acrylic Justification for difference: The material has been evaluated to ISO 10993-1 & ISO 18562-1 and found to be safe and effective.	Different Polypropylene and acrylic Justification for difference: The material has been evaluated to ISO 10993-1 & ISO 18562-1and found to be safe and effective.
Device Body	Acrylic copolymer	Similar Acrylic polymer Justification for difference: This material has been evaluated to ISO 10993-1& ISO 18562-1 and found to be safe and effective.	Same as predicate

Substantial Equivalence – Summary of Performance Testing
The following performance testing were performed in support of the substantial equivalence determination:

Biocompatibility testing
The biocompatibility evaluation was conducted in accordance with FDA Guidance "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"'* June 16, 2016, ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*" and ISO 18562-1 *Biocompatibility evaluation of breathing gas pathways in healthcare applications − Part 1: Evaluation and testing within a risk management process*".

The biocompatibility tests for external communicating with tissue/bone/dentin with limited (less than 24 hours) include: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity, as well as an assessment to demonstrate compliance to the ISO 18562 standard series, including volatile organic compounds and particulate matter testing. The subject device met all biocompatibility requirements for its intended use.

Bench Testing
Performance bench testing including color change/duration of use, resistance to flow, internal volume(dead space), anti-fog, shelf-life, packaging stability and biocompatibility were performed on the subject devices to verify the designs meet performance specification and evaluation.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence.

Substantial Equivalence – Conclusions
The subject device and the predicate device have the same intended use and the differences in technological features do not raise different questions of safety and effectiveness. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.