July 20, 2020

Covidien llc
Ligia Mastronardi
Regulatory Affairs Manager
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K201179
Trade/Device Name: GE ApexPro CH SpO2 - Nellcor Cable, GE ApexPro FH SpO2 - Nellcor Cable
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 30, 2020
Received: May 1, 2020

Dear Ligia Mastronardi:

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 below.

510(k) Number *(if known)*
K201179

Device Name
GE ApexPro CH SpO2 – Nellcor cable
GE ApexPro FH SpO2 – Nellcor cable

Indications for Use *(Describe)*

GE ApexPro CH SpO2 – Nellcor cable

The GE ApexPro CH SpO2 – Nellcor cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonate, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.
• Note: Hospital use typically includes such areas as the intensive care unit (ICU), Pediatric Intensive Care Unit (PICU), neonatal intensive care unit (NICU),and medical/surgical general care floor (GCF).
• Note: Hospital-type facilities include step-down units and longterm care facilities.

GE ApexPro FH SpO2 – Nellcor cable

The GE ApexPro FH SpO2 – Nellcor cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.
• Note: Hospital use typically includes such areas as the intensive care unit (ICU), Pediatric Intensive Care Unit (PICU), neonatal intensive care unit (NICU), and medical/surgical general care floor (GCF).
• Note: Hospital-type facilities include step-down units and longterm care facilities.

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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Medtronic

510(k) Summary

The 510(k) summary for the GE ApexPro CH SpO2 – Nellcor Cable "&" GE ApexPro FH SpO2 – Nellcor Cable outlined below is written 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.

K201179

SUBMITTER INFORMATION:

Submitted By: Covidien, llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Date: July 1, 2020

Contact Person: Lígia Mastronardi
Regulatory Affairs Manager
Phone: (303) 912-7752
Fax: N/A
ligia.mastronardi@medtronic.com

SUBJECT DEVICE NAME

Proprietary Name: GE ApexPro™ CH SpO2 – Nellcor Cable
GE ApexPro™ FH SpO2 – Nellcor Cable[1]

Common Name: SpO2 Cable

Classification Name: Oximeter

Device Classification Regulation: 21 CFR 870.2700 – Class II

Regulation Medical Specialty: Cardiovascular

Device Product Code: DQA

510k Review Panel: Anesthesiology

[1] Collectively called GE ApexPro CH/FH SpO2 - Nellcor Cables throughout this submission.

PREDICATE DEVICE

Manufacturer: Covidien, llc

Device Name: The Nellcor Pulse Oximetry Monitor Interface Cable

510(k) number: K172482

Clearance Date: 12/15/2017

Subject Device Description

The subject device of this premarket 510(k) notification is composed of two (2) cables as follows:

- GE ApexPro CH SpO2 – Nellcor Cable
- GE ApexPro FH SpO2 – Nellcor Cable

Collectively, the two cables are referred to as GE ApexPro CH/FH SpO2 – Nellcor Cable throughout this submission.

The GE ApexPro CH/FH SpO2 – Nellcor Cable (subject device) is a that provides an external oximetry-in-a-cable solution when used with the GE ApexPro™ Telemetry System and a Nellcor™ pulse oximetry sensor with Oximax™ technology. The subject device is used as part of the GE ApexPro Telemetry System that provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate which is measured by Nellcor pulse oximetry sensors. The GE ApexPro Telemetry System provides clinicians with patient data while allowing for patient mobility. The GE ApexPro Telemetry System was cleared by the FDA on June 20, 2008 under 510(k) number K080251.

The GE ApexPro FH/CH SpO2 - Nellcor cable is a modification of the Nellcor Pulse Oximetry Monitor Interface Cable (K172482) which is used as an interface when used with the GE ApexPro Telemetry System.

The device description from the subject device labeling is provided in Table 1.

Table 1 – Subject Device Description

	GE ApexPro™* CH SpO2 – Nellcor Cable	**GE ApexPro™* FH SpO2 – Nellcor Cable**
Device Description	When used with a GE ApexPro™ telemetry system, the GE ApexPro™ CH SpO2 – Nellcor cable (SpO2 oximetry cable) provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, as measured by Nellcor™ pulse	When used with a GE ApexPro™ FH telemetry system, the GE ApexPro™ FH SpO2 – Nellcor cable (SpO2 oximetry cable) provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, as measured by Nellcor™ pulse

	oximetry sensors. The SpO2 oximetry cable relies on unique oximetry technology and design to provide hospitals, clinicians, and caregivers with accurate, timely data. The SpO2 oximetry cable must be used with a GE ApexPro™ telemetry system. The SpO2 oximetry cable provides the following vital signs for display: •• Arterial blood oxygen saturation (SpO2) •• Pulse rate (PR) •• Measurement confidence indicator	oximetry sensors. The SpO2 oximetry cable relies on unique oximetry technology and design to provide hospitals, clinicians, and caregivers with accurate, timely data. The SpO2 oximetry cable must be used with a GE ApexPro™ FH telemetry system. The SpO2 oximetry cable provides the following vital signs for display: •• Arterial blood oxygen saturation (SpO2) •• Pulse rate (PR) •• Measurement confidence indicator
Host Details	The GE ApexPro Telemetry System was cleared by the FDA on June 20, 2008 under 510(k) number K080251.	
Compatible Sensors	Nellcor™ pulse oximetry sensors with Oximax™ technology and compatible for use with the GE ApexPro™ CH SpO2 – Nellcor cable with respective 510(k) numbers are outlined below: - Forehead SpO2 sensor: MAXFAST (K012891) - Non-adhesive SpO2 sensors: SC-A, SC-NEO, SC-PR (K030930) - Adhesive SpO2 sensors: MAXA/MAXAL, MAXN, MAXI, MAXP (K012891) - SpO2 sensors: A, N, I, P (K012891) - Reusable SpO2 clip sensors:DS100A, D-YSPD, D-YS, D-YSE (K012891) - Reusable SpO2 clip sensors: FLEXMAX, FLEXMAS-P (K162014) - Two-piece reusable SpO2 sensors: OXI-A/N, OXI-P/I (K012891) - Nellcor™ adult SpO2 nasal sensor: MAX-R (K012891)	

Intended Use/Indications for Use

GE ApexPro CH SpO2 – Nellcor Cable

The GE ApexPro CH SpO2 – Nellcor Cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonate, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.

• Note: Hospital use typically includes such areas as the intensive care unit (ICU), Pediatric Intensive Care Unit (PICU), neonatal intensive care unit (NICU), and medical/surgical general care floor (GCF).

• Note: Hospital-type facilities include step-down units and long-term care facilities.

GE ApexPro FH SpO2 – Nellcor Cable

The GE ApexPro FH SpO2 – Nellcor Cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.

• Note: Hospital use typically includes such areas as the intensive care unit (ICU), Pediatric Intensive Care Unit (PICU), neonatal intensive care unit (NICU), and medical/surgical general care floor (GCF).

• Note: Hospital-type facilities include step-down units and long-term care facilities.

Technological Characteristics Comparison

The subject device, the GE ApexPro CH/FH SpO2 - Nellcor Cable has the same intended use, similar indications for use, principles of operation, and fundamental technology as the predicate device, the Nellcor Pulse Oximetry Monitor Interface Cable (K172482). The subject device is a derivative of the predicate device with software and hardware modifications.

Results of verification and validation testing support the use of the GE ApexPro CH/FH SpO2 - Nellcor cable with GE ApexPro Telemetry Systems and with the same Nellcor SpO2 sensors commercially available for use with the predicate device.

Based on results of verification and validation studies (including system verification), Covidien has established that the subject device, the GE ApexPro™ CH/FH SpO2 - Nellcor Cable is substantially equivalent to the predicate device.

Substantial Equivalence – Non-Clinical Evidence

The performance testing section of this submission includes verification and validation reports for pulse oximetry performance were conducted in accordance with FDA Guidance document: “Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff”. Bench Performance Testing conducted includes, but is not limited to testing outlined below:

- Testing conducted per ISO 80601-2-61:2017 and IEC 60601-1:2005 + A1:2012 standards
- Oximetry performance verification testing in low perfusion conditions

Substantial equivalence was determined through results from verification & validation testing and testing conducted per standards as indicated below:

- System Verification
- Software Verification
- Hardware Verification
- Compatibility Verification
- Compliance testing to the following standards:

    - IEC 60601-1:2005 + A1:2012

- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 62366-1:2015/ COR1:2016
- ISO 80601-2-61:2017
- ISO 15223-1:2016
- IEC 62304:2006+AMD1:2015
- ISO 10993-1:2018

The results of this testing demonstrate that the subject device, the GE ApexPro CH/FH SpO2 - Nellcor Cable, can be considered as substantially equivalent to the predicate device.

Substantial Equivalence – Clinical Evidence

N/A – Clinical evidence was not necessary to show substantial equivalence. Please refer to Table 2 for Substantial Equivalence comparison.
The Substantial Equivalence Table is provided below:

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Table 2: Substantial Equivalence

Device Characteristics	**Predicate Device:** The Nellcor Pulse Oximetry Monitor Interface Cable – 510(K) 172482 (“Oxicable”)	**Subject Devices:** GE ApexPro CH SpO2 – Nellcor Cable GE ApexPro FH SpO2 – Nellcor Cable	**Similarities and Differences**
Device Pictures		GE ApexPro CH SpO2 – Nellcor Cable:  GE ApexPro FH SpO2 – Nellcor Cable: 	Visually different
Indications for Use	The Nellcor™ USB Pulse Oximetry Monitor Interface Cable is indicated for prescription use only for spot check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.	The GE ApexPro™ CH/FH SpO2 – Nellcor cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.	Similar
Prescription/Over-the-counter Use	Prescription	Prescription	Similar
Intended Use Populations	Neonatal, Pediatric, and Adult populations	Neonatal, Pediatric, and Adult populations	Similar

Environment of Use	Hospitals, hospital-type facilities. Note: Hospital use typically includes such areas as the intensive care unit (ICU), neonatal intensive care unit (NICU), operating room (OR), post-anesthesia care unit (PACU), emergency department, and medical/surgical general care floor (GCF). Note: Hospital-type facilities include step-down units and longterm care facilities.	Hospitals, hospital-type facilities. Note: Hospital use typically includes such areas as the intensive care unit (ICU), Pediatric Intensive Care Unit (PICU), neonatal intensive care unit (NICU),and medical/surgical general care floor (GCF). Note: Hospital-type facilities include step-down units and longterm care facilities.	Similar
Measurement Parameters	Oxygen Saturation, Pulse Rate	Oxygen Saturation, Pulse Rate	Similar
Sensor Compatibility	Use only Nellcor-approved sensors.	Use only Nellcor-approved sensors.	Similar
Intended Application Site	NA – Device not in direct contact with the patient.	NA – Device not in direct contact with the patient.	Similar
Performance Characteristics and Specifications			
SpO_2 Technology	Spectrophotometry and plethysmography	Spectrophotometry and plethysmography	Similar
SpO_2 Algorithm	Comparison of red/infrared modulation %	Comparison of red/infrared modulation %	Similar
SpO2 measurement range (%)	1% to 100%	1% to 100%	Similar
SpO2 Measurement Accuracy Specifications			
Without motion – Adults	70-100% ±2 digits	70-100% ±2 digits	Similar
Without motion – Neonates	70-100% ±2 digits	70-100% ±2 digits	Similar
With motion – Adults & Neonates	70-100% ±3 digits	70-100% ±3 digits	Similar
Low Perfusion	70-100% ±2 digits	70-100% ±2 digits	Similar
LoSat	60% to 80%±3 digits	60% to 80% ±3 digits	Similar
Pulse Rate Measurement Range (BPM) and Accuracy			
Without Motion (Adult & Neonate)	20 to 250 BPM ±3 digits	20 to 250 BPM ±3 digits	Similar
With Motion	20 to 250 BPM ±5 digits	20 to 250 BPM ±5 digits	Similar

Low Perfusion	20 to 250 bpm ±3 digits	20 to 250 bpm ±3 digits	Similar
Safety Specifications			
Electrical	IEC 60601-1-2:2007 IEC 60601-1-2:2014 IEC 60601-1:2005/AMD1:2012	IEC 60601-1-2:2014 IEC 60601-1:2005/AMD1:2012	Subject device meets current standards.
Environmental	Operating Temperature: 5ºC to 40ºC (41ºF to 104ºF) Operating Atmospheric Pressure: 1075 hPa to 616 hPa Operating Relative Humidity: 15% to 95% non-condensing Transport and Storage Temperature: -40ºC to 70ºC (-40ºF to 158ºF) Transport and Storage Operating Atmospheric Pressure: 1075 hPa to 500 hPa Transport and Storage Operating Relative Humidity: 15% to 95% non-condensing	Operating Temperature: 5ºC to 40ºC (41ºF to 104ºF) Operating Atmospheric Pressure: 1075 hPa to 616 hPa Operating Relative Humidity: 15% to 95% non-condensing Transport and Storage Temperature: -40ºC to 70ºC (-40ºF to 158ºF) Transport and Storage Operating Atmospheric Pressure: 1200 hPa to 475 hPa Transport and Storage Operating Relative Humidity: 10% to 95% non-condensing	No operating differences. Transport and storage differences due to overlaps and extensions beyond those of predicate device.
Mechanical	IEC 60601-1:2005/AMD1:2012	IEC 60601-1:2005/AMD1:2012	Similar
Features			
Portability	Portable	Portable (Body-worn)	Different: Subject device can be worn by the patient or attached to a patient's clothing.
Alarms	N/A-The host monitor is responsible for detecting, triggering, prioritizing, and notifying the operator of the alarm conditions.	N/A-The GE ApexPro telemetry system is responsible for detecting, triggering, prioritizing, and notifying the operator of the alarm conditions.	Similar
Indicators	N/A-No Indicator	N/A-No Indicator	Similar

Modes	Working Mode: Continuous Mode Response Mode: Normal Response Mode, Fast Response Mode. Power Mode: Legacy Power Mode, Normal Power Mode, Low Power Only Mode	Working Mode: Continuous Mode Response Mode: Normal Response Mode Power Mode: Normal Power Mode	Different: Subject device only sends message to host. Predicate device sends to and receives messages from host. See impact below.
Display	N/A – readings are displayed by the Host Monitor at the central station	N/A – results are displayed by the Host Monitor at the central station	Similar
Power Source	Energy source is provided by host which is powered by main via USB connection.	Energy source is provided by host's battery operated transceiver or transmitter.	Different: Change of energy source
Physical Features	Includes second bump (ISO) as the line module consists of patient isolation, power regulation, current limitation and USB communication interface.	No second bump required. Power regulation, current limitation, and serial communication interface are provided by Boost Board embedded in the cables.	Different: ISO bump versus boost board. See impact below.
	USB Type A connector	GE ApexPro CH/FH connector, with power converter overmolded	Different: Different connector due to different hosts.
	Length: 305 cm long	FH Length: 37 cm long CH Length: 32.5 cm long	Different: Different length due to different hosts.
Function			
Device Functionality	Host: Qualified host display monitor.	Host: GE ApexPro CH/FH Telemetry Systems (K080251)	Similar
	Provides patient isolation protection	No additional isolation forming MOPP needed in U-NSAT	Different: MOPP variance is due to different energy sources.
	Bidirectionally communicates (sends and receives information) with externally interfaced host monitor	Unidirectionally communicates with externally interfaced host monitor. Cable will only send information to GE ApexPro CH/FH Telemetry Systems	Different: Unidirectional communication versus bidirectional.

	UtilizesUSB 2.0 full speed VCP (Virtual Communications Port) driver to communicate with externally interfaced host monitor.	Utilizes UART (Universal Asynchronous Transmitter Receiver) protocol to communicate with externally interfaced host monitor.	Different: Different communication protocol due to different hosts.
Software Communication Protocols	Communication protocol: Covidien Standard Protocol	Communication protocol: ASPIP (GE Protocol)	Different: Different communication protocol due to different hosts.
Signal Strength Indicator	None	Asterisk system	Subject device host monitor will display ***/**/* will be displayed to indicate the SSI).

Software and Cybersecurity

Software Description:

The subject device GE ApexPro CH/FH SpO2 - Nellcor Cable is an interface cable with the pulse Oximetry engine embedded in its PCBA. The cable connects to the GE ApexPro FH and CH telemetry system and communicates via UART protocol via a wired connection.

The Oximetry PCBA in the subject device contains an embedded software that uses the Nellcor pulse oximetry algorithm to calculate SpO2 (oxygen saturation in the body) and PR (pulse rate) for both motion and non-motion conditions.

Embedded software also includes a GE ASPIP software protocol to communicate with GE ApexPro FH and CH telemetry system. Features include SpO2, PR, SSI and sensor status (i.e., sensor off the patient, sensor disconnected) which are reported to the GE ApexPro telemetry system.

The software is executed on a single processor. Additionally, the software does not use an operating system or off the shelf software.

Cybersecurity Summary:

The GE ApexPro CH/FH SpO2 – Nellcor cable do not include wireless communication capability for communication to a host. Communication to a host is accomplished via a wired connection using the UART protocol. Any changes to the cable (like software updates) are carried out via custom software tools that are only available to Medtronic / trained technicians.

The device is designed so that it does not store any protected health information. Access to the software update protocols, the specialized hardware, the software update application is limited to Medtronic / trained technicians. Cybersecurity controlled access is accomplished through design that prevents any control signals from being sent to the host device and by of the inability to store patient identifiers. These features were evaluated and determined to meet controlled access needed for cybersecurity.

The GE ApexPro CH/FH SpO2 – Nellcor cable communicates to the GE ApexPro telemetry system through a wired connection using the UART protocol. Wireless communication is not a feature of the device. Thus, a cybersecurity incident affecting the device could only directly affect a single patient. The GE ApexPro CH/FH SpO2 – Nellcor cables are considered as Tier 2 “Standard Cybersecurity Risk” as defined in FDA guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (May, 2005).

Any software-related vulnerabilities of GE ApexPro CH/FH SpO2 – Nellcor cable are identified, scored and mitigated through the vulnerability assessment process.

Biocompatibility Information

The subject device GE ApexPro CH/FH SpO2 – Nellcor Cable is a non-sterile medical device that may intermittently come into direct skin contact with the patient.

A list identifying each of tissue-contacting device components and associated materials of construction for each component, including identification of color additives are provided in Table 3 below.

Table 3. Tissue contacting Subject Device Components and Materials

Component			GE ApexPro FH SpO2 Nellcor cable	GE ApexPro CH SpO2 Nellcor cable
Host connector over-mold		Material	(Thermoplastic polyurethanes, GRAY MUNSELL N7)	
		Patient contact	Yes	
Clear coat		Material	Tampa Star TPR 910 ink + H1 hardener	
		Patient contact	Yes	
Assy, Oxicor-Unlabeled		Part Number	PT00092575	
Subcomponent	Oxicor over-mold	Material	PELLETHANE (PANTONE 281C)	
		Patient contact	Prolonged exposure	
	Cable outer jacket	Material	POLYURETHANE, PANTONE COOL GRAY 9C	
		Patient contact	Yes	
	Sensor latch	Material	POLYCARBONATE	
		Patient contact	Yes	

The GE ApexPro CH/FH SpO2 – Nellcor Cable is considered to be a surface device with intact skin contact of prolonged duration (>24 hours to 30 days) per ISO 10993-1 and FDA Use of International Standard ISO 10993-1, “Biological evaluation of medical devices-Part 1: Evaluation

and testing within a risk management process". Therefore, cytotoxicity, sensitization, and irritation testing were conducted with the subject cables.

A Biocompatibility Assessment was conducted for GE ApexPro CH/FH SpO2 – Nellcor cable to review the material information, applicable data, and results of the biological safety tests required to support the biocompatibility of this device for its intended use. This assessment was performed in accordance to ISO 10993-1-Part 1 and the FDA Guidance Document entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"."

Based on ISO 10993-1 and the FDA guidance: Use of International Standard ISO 10993-1, the following tests were performed with the subject device:

- Cytotoxicity,
- Sensitization
- Irritation

The results of all testing showed that GE ApexPro CH/FH SpO2 – Nellcor cable poses negligible risk of cytotoxicity, sensitization and irritation for human use.

Pulse Rate and Spo2 Accuracy Bench Testing Conducted

Table 4 provides the bench testing studies that were conducted to verify the subject device performance for to Pulse Rate and SpO2 accuracy:

Table 4. Pulse rate and SpO2 Accuracy Bench Testing

Report No.	Report Title	Report Conclusions
RE00238214	Motion Pulse Rate Accuracy Verification Test Report, GE ApexPro CH/FH SpO2-Nellcor cable	This report confirms the pulse rate accuracy of GE ApexPro CH/FH SpO2 – Nellcor cable under simulated motion conditions using a pulse simulator device per the following: ▪ Pulse rate accuracy is evaluated under motion conditions in the range of 25 -250 beats per minute at a fixed O_2 saturation of 95% and a Modulation% of 3% during quiescent periods, or as close as the pulse simulator was able to produce. ▪ Pulse rate and SpO2 performance is measured using the calculated RMSD (root mean square of the difference) of the simulated pulse rate input and the DUT displayed pulse rate.
RE00238211	System Performance Verification Test Report, GE ApexPro CH/FH SpO2-Nellcor cable	This report confirms that the GE ApexPro CH/FH SpO2 – Nellcor cable meets SpO2 and Pulse Rate range and accuracy requirements by the following: ▪ Reporting pulse rate values between 20 and 250 (bpm) inclusive ▪ Reporting SpO2 values between 1 and 100 %

RE00238215	Basic Performance Verification Test Report, GE ApexPro CH/FH SpO2 – Nellcor cable	This report confirms that the GE ApexPro CH/FH SpO2 – Nellcor cable meets SpO2 and pulse rate accuracy requirements by reporting SpO2 and pulse rate values.
RE00238216	Benchtop Low Perfusion Accuracy Verification Test Report, GE ApexPro CH/FH SpO2 – Nellcor cable	This report confirms that the GE ApexPro CH/FH SpO2 – Nellcor cable meets sensor accuracy requirements for low perfusion by calculating the RMSD (Root Mean Square Difference) values and verifying that the reported SpO2 values meet the accuracy requirements for the different sensors.
RE00238217	Sensor Failure Verification Test Report, GE ApexPro CH/FH SpO2-Nellcor cable	This report confirms that the GE ApexPro CH/FH SpO2 – Nellcor Cable meets Sensor Interface requirements by simulating sensor faults (i.e., sensor unrecognized or sensor off) and by verifying that errors (such as boot errors) are reported as per Software Requirements Specification, GE ApexPro FH/CH SpO2-Nellcor cables within the time specified in the requirements.
RE00238213	Ambient Light Step Response Verification Test Report, GE ApexPro CH/FH SpO2-Nellcor cable	This report confirms that the GE ApexPro CH/FH SpO2 – Nellcor Cable meets requirements by changing the levels and verifying the time taken for the system to respond. This report also confirms that the system recovers after removal of excessive ambient light from the sensor.
RE00238210	Device and Sensor States Verification Test Report, GE ApexPro CH/FH SpO2-Nellcor cable	This report confirms that GE ApexPro CH/FH SpO2 – Nellcor Cable meets the following: • Reports Sensor connected/sensor disconnected status to host • Communicates with GE telemetry system when no sensor connected • Start communicating after power on/reset • Reports Device ID • Reports device status bytes • Sends Low battery status • Sends invalid SPO2 and PR when sensor disconnected • Reports Invalid SPO2 and invalid PR • Reports Low perfusion and Marginal perfusion Communicates with host when input voltage within required interface range.

Substantial Equivalence – Conclusions

Substantial equivalence of the subject device to the predicate device was determined by comparison that showed that the devices have same intended use ,similar technological characteristics, indications for use, and principles of operation. The, Software and hardware modifications were made to the subject device, GE ApexPro CH/FH SpO2 - Nellcor Cable in

order to maintain the intended performance of the device and to enable interface to the GE ApexPro Telemetry Systems.

No new questions regarding safety and effectiveness have been raised because of these modifications and addition of features. The difference in technological features of the subject device compared to the predicate device does not raise different questions of safety and effectiveness. Based on the evidence presented in this Premarket Notification, the subject device can be considered substantially equivalent to the predicate device.