CMI Health Inc.
% Charles Mack
Principal Engineer
International Regulatory Consulting
7808 Rush Creek Drive
Pasco, Washington 99301

Re: K170820
Trade/Device Name: Capnograph and Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, CCK
Dated: June 16, 2018
Received: June 22, 2018

Dear Charles Mack:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K170820

Device Name
Capnograph and Oximeter, Capno-H

Indications for Use *(Describe)*

The Capnograph and Oximeter is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate.

The Capnograph and Oximeter is intended for use in adults in a hospital environment. It is intended to be used only under regular supervision of clinical personnel

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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 18, 2018

Submitter Information		
	Submitter name	CMI Health Inc.
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US Agent and Correspondent		
	Name	Mr. Charles Mack
	Address	7808 Rush Creek Drive Pasco, Washington 99301
	Telephone	1931-625-4938
	Email	charliemack@irc-us.com
Subject Device	Trade Name	Capnograph and Oximeter Model Capno-H
	Common Name	Oximeter
	Regulation Number	21 CFR 870.2700
	Regulation Name	Oximeter
	Regulation Class	Class II
	Product Code	DQA, CCK
	Classification Panel	Anesthesiology

Predicate Device	Trade Name	Vital Signs Monitor, Model PC-900A
	510(k) Number	K093016
	Common Name	Oximeter
	Regulation Number	21 CFR 870.2700
	Regulation Name	Oximeter
	Regulation Class	Class II
	Product Code	DQA, CCK
	Classification Panel	Anesthesiology

Purpose of Submission:

This is a new submission of an oximeter and capnograph, Capnograph and oximeter, model Capno-H, submitted by CMI Health Inc. There have been no previous submissions of this product.

Device Description:

This device is used to monitor up to four physiological parameters for the patient at the same time: End tidal CO2 concentration (EtCO2), Respiration Rate (RR), functional Oxygen Saturation (SpO2) and Pulse Rate (PR). The monitor can be purchased having functions with two or more of the parameters mentioned above, but the manual can be used for the device in any configuration.

<u>EtCO2</u>

Method: Proprietary non-dispersive infrared spectroscopy

Range: 0 – 150mmHg or 0 – 20kPa or 0 – 19.7% (v/v)

Accuracy: ±2mmHg for EtCO2 range 0 - 40mmHg
±5% for EtCO2 range from 41 - 70mmHg
±8% for EtCO2 range from 71 - 100mmHg
Over 100mmHg ±10%

Respiration Rate

Range: 3 - 150 breaths/minute

Accuracy: ±1% of reading or ±1 breaths/min whichever is greater

Memory: 24 hours on Screen Trend and Numeric

SpO2

Method: Patented Proprietary Pulse Oximetry

Range: 0- 100%

Accuracy: ±3% for SpO2 range from 70 - 100%

Memory: 24 hours on Screen Trend and Numeric

Pulse Rate

Range: 30 – 240bpm

Accuracy: ±2% of reading or ±2bpm whichever is greater

Memory: 24 hours on Screen Trend and Numeric

Power

AC Input: 100V - 250V, 50Hz/60Hz to 5VDC Adapter
with 5V mini USB adapter Cable.

Battery

Type: Built-in rechargeable lithium battery pack (3.6V, 3000mAH)

Charging Time: 4 hours from full discharge

Operating Time: 10 hours on full charge

The Capno-H uses an infrared absorption method to measure in a sidestream or Mainstream mode. The measurement parameters are $EtCO_2$, $InsCO_2$ and Respiration Rate. $InsCO_2$, also called FiO_2 is the fraction of oxygen in the volume being measured. The CO_2 response time is Sidestream: <3seconds (includes transport time and rise time) and Mainstream: <60ms (rise time). The unit of measurement is mmHg, kPa or Vol%. The CO_2 measurement range is $EtCO_2$: 0~150mmHg and $InsCO_2$: 3~50mmHg.

The SpO2 measurements are also determined by infrared absorption. The measurement range is 0-100% at an accuracy of ±3% for SpO2 range from 70 - 100% with a pulse rate range of 30-240 bpm at an accuracy of +/- 2bpm or +/- 2% (whichever is greater). For SpO2 and bpm, there are configurable high and low alarms.

Indication for use:
The Capnograph and Oximeter is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate.

The Capnograph and Oximeter is intended for use in adults in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.

SUBJECT ***Indications for Use***	**PREDICATE** **(K093016)** ***Indications for Use***
The Capnograph and Oximeter is designed for monitoring the vital physiological signs of the patient. It is use for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate. The Capnograph and Oximeter is intended for use in adults in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.	The Vital Signs Monitor is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate. The Vital Signs Monitor is adaptable to adult and pediatric usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.

The summaries of both the submitted Capno-H Capnograph and Oximeter are exactly the same, with a difference in the patient population. The submitted device is intended for use by adults and not pediatric patients. This does not change the intended use.

Comparison with predicate device:

Both the submitted CMI Health Inc. Capnograph and Oximeter, Model Capno-H and the Shenzhen Creative Industry Co., Ltd, Vital Signs Monitor, Model PC-900A are used for monitoring the vital physiological signs of the patient. Both are used for non-invasive continuous monitoring of oxygen saturation (SpO2), Pulse Rate, CO2 and Respiration Rate.

The submitted device and predicate both are used for continuous monitoring of CO2 concentration (EtCO2), Respiration Rate (RR), functional Oxygen Saturation (SpO2) and Pulse Rate (PR), utilizing the same technology.
Both the submitted device and the predicate device have plastic cases and these have been biocompatibility tested for patient contact.

Technological Characteristics:

The submitted Capno-H utilizes the predicate's SPO2 module for SPO2 functions. For the CO_2 function, the Capno-H uses the infrared absorption method with a side stream measurement mode, the same as the predicate. Please refer to the tables on the following pages for specific differences.

At a high level, the submitted Capno-H and the predicate Shenzhen Device serve the same functions:

- Devices are used to measure SPO_2, CO_2, pulse rate and respiration rate in adult patients. The submitted Capno-H device is not used for pediatric patients.

- Both devices are portable and use a LED and LCD display to read the measured data

- Both devices use the same methodology for measuring SPO_2, CO_2, pulse rate.

- The submitted device and the predicate device have alarms for $EtCO_2$, SPO_2 and respiration rate.

Please refer to the following table for a comparison of specific elements of the predicate device and the submitted device.

Comparison with Legally Marketed Predicate Device

Element of comparison	Subject Device	Predicate Device	Discussion
Company	CMI Health Inc.	Shenzhen Creative Industry Co., Ltd.	N/A
FDA510(K) Number	N/A	K093016	N/A
Device Name	Capnograph and Oximeter	Vital Signs Monitor	N/A
Model Number	Capno-H	PC-900A	N/A
Indications for Use	The Capnograph and Oximeter is designed for monitoring the vital physiological signs of the patient. It is use for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate. The Capnograph and Oximeter is adaptable to adult usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.	The Vital Signs Monitor is designed for monitoring the vital physiological signs of the patient. It is use for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate. The Vital Signs Monitor is adaptable to adult and pediatric usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.	Identical
Power Supply	Battery or AC	Battery or AC	Identical
Internal Power Supply	Rechargeable lithium battery, 3.6V 3.0AH	Rechargeable sealed lead-acid battery, 12V 2.3AH	All Comply with IEC requirement
AC Power Supply	100V - 250V, 50Hz/60Hz DC5V Unit Consume:≤5VA	100~250V 50/60Hz 90VA	Much lower power consumption than the Predicate device, as we adopt chips with lower power consumption and power management circuit with higher efficiency and meanwhile these circuits have passed the test of IEC 60601-1 and IEC 60601-1-2.
The type of protection against electric shock	Class I and internally powered per IEC 60601-1.	Class I and internally powered per IEC 60601-1.	Identical
The degree of protection against electric shock	Type BF	Type BF	Identical

Element of comparison	Subject Device	Predicate Device	Discussion
Display	LED and LCD display	LED and LCD display	Identical
Dimensions(mm)	72(L) × 40(W) × 155(H)	360(L) × 320(D) × 410(H)	N/A
Intended patient population	Adult patients	Adult, pediatric patients	Identical
Nurse call function	Yes	Yes	Identical
SpO_2			
SpO_2 module	PC-60 SpO_2 module cleared in K063641	PC-60 SpO_2 module cleared in K063641	Identical. Same SpO2 module as Predicate which the sensors were clinically validated and intended to be used in K063641
SpO_2 display range	0%~100%	0%~100%	Identical
SpO_2 measure range for accuracy	70-100%	70%~99%	Identical
Accuracy of SpO_2	Adult: ±3% (during 70%~100%) Undefined (during 0~70%)	Adult and Pediatric: ±3% (during 70%~99%) Undefined (during 0~70%)	Identical
Alarm of SpO_2	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	Identical
Pulse rate display range	30 bpm~240 bpm	30 bpm~240 bpm	Identical
Accuracy of pulse rate	±2bpm or ±2% (whichever is greater)	±2bpm or ±2% (whichever is greater)	Identical
Alarm of pulse rate	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	Identical

Element of comparison	Subject Device	Predicate Device	Discussion
Operation principles	This monitor measures the pulse oxygen saturation (SpO_2) and pulse by means of the radiograph of infrared light and the red light emitted by LED through body's peripheral areas (such as fingers), whereby the photoelectric detecting circuits will analyze the absorptivity of the oxyhemoglobin and reduced hemoglobin respectively, and give the photo absorption rates before and after pulsation. Using the measure of photo absorption change due to pulsatory arterial blood flow caused by PLETH waveform, the SpO_2 can be obtained.	This monitor measures the pulse oxygen saturation (SpO_2) and pulse by means of the radiograph of infrared light and the red light emitted by LED through body's peripheral areas (such as fingers), whereby the photoelectric detecting circuits will analyze the absorptivity of the oxyhemoglobin and reduced hemoglobin respectively, and give the photo absorption rates before and after pulsation. Using the measure of photo absorption change due to pulsatory arterial blood flow caused by PLETH waveform, the SpO_2 can be obtained.	Identical
CO_2			
CO_2 module	CapnoCore	Respironics LoFlo™ EtCO2 (Side-stream) Module(K053174) and CAPNOSTAT 5 EtCO2 (Main-stream) Module(K042601)	N/A
CO_2 measurement method	Infrared absorption method	Infrared absorption method	Identical

Element of comparison	Subject Device	Predicate Device	Discussion
CO_2 measure mode	Sidestream	Sidestream OR Mainstream	- The Predicate device can use Sidestream OR Mainstream to measure CO2, these two models can not coexist /work at the same time in clinical use and can only choose one way to measure; -The CO2 module of Predicate device is external, but new device is built-in. It doesn't affect the measurement; -The operation principle of Sidestream module is same as Predicate device's; - The new device is complying with ISO80601-2-55 for the Particular requirements for the basic safety and essential performance of respiratory gas monitors same as Predicate device;
Measuring parameters	$EtCO_2$, $InsCO_2$ and Respiration Rate	$EtCO_2$, $InsCO_2$ and Respiration Rate	Identical
CO_2 Response Time	<1second	Sidestream: <3seconds (includes transport time and rise time). Mainstream: <60ms (rise time)	CO_2 response time depends on the length of the sample line. If we adopt sampling line with 1.5 meter long, the time of the gas transmission and uprising will be less than 1 seconds, this time is shorter than that of the Predicate device. Response time is the shorter the better. But to monitoring device, the one second difference of response time will not influence the usage effect.
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	Identical

Element of comparison	Subject Device	Predicate Device	Discussion
CO_2 measure range	$EtCO_2$: 0~150mmHg $InsCO_2$: 3~50mmHg	$EtCO_2$: 0~150mmHg $InsCO_2$: 3~50mmHg	Identical
CO2 Accuracy	0~40 mmHg ±2mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg±10% of reading	0~40 mmHg ±2mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg±10% of reading	Identical
Respiration Rate measure range	3 - 150 breaths/minute	2~150rpm (Sidestream) or 0~150rpm (Mainstream)	For adults, 2 RPM of respiration rate will be abnormal. This device will alert and the medical professional when respiration drops below this rate.
Respiration Rate accuracy	±1% of reading or ±1 breaths/min whichever is greater	±2rpm	Identical
Flow Rate	50–250cc/min	50ml/min ±10 ml/min (Sidestream)	Sampling flux can be adjusted, which does not influence measurement accuracy of CO2 concentration and respiration frequency.
NO CO_2 Detected Alarm Delay	15~39s off	10~60s	NO CO_2 Detected time alarm is controlled by doctor, which is as same as the Predicate device so there is no new risk.
Alarm of $EtCO_2$	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	Identical
Alarm of RR	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	Identical

Element of comparison	Subject Device	Predicate Device	Discussion
Operation principles	The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, the electronic signal from an infrared sensor (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrated, the infrared sensor's response to a known concentration of CO_2 is stored in the monitor's memory. Further, on the passage of the sample gas with a three-way valve, with the change of temperature and time, the valve leading to the pure air will 3-4 seconds in order to adjust the zero point. In addition, the circuit module has the atmospheres absolute pressure sensors and the flow measurement and control of pressure sensor. Modules can measure atmospheric pressure, and atmospheric pressure can compensate the calculation for the concentrations of carbon dioxide which improve the design accuracy. Then the monitor (CO2 module) determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases.EtCO_2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.	The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, the electronic signal from a photodetector (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrated, the photodetector's response to a known concentration of CO_2 is stored in the monitor's memory. The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases.EtCO_2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.	Identical. This device uses different CO2 module CapnoCore from the Predicate device uses CO2 module (Loflo module) but its measurement technology principle is same. Both of them adopt NDIR (non-dispersive infrared gas) technology. The difference of CapnoCore module and Loflo module is that the former has three-way valve with automatically zero calibration and barometric pressure sensor so as to avoid manual zero calibration and manual inputting barometric pressure.
Materials	the upper case : ABS battery cover : ABS the lower case : ABS SpO_2 module: K063641	Front housing : ABS battery cover : ABS rear housing : ABS SpO_2 module: K063641	Identical. All comply with ISO10993-1 Biocompatibility requirement.

Modules Used in Capno-H

	CO_2 Side stream	SpO_2
Company	Beijing Kingst Commercial & Trade Co., Ltd.	Shenzhen Creative Industry Co., Ltd.
Model	CapnoCore	Creative Oximeter with the same principle as PC-60
FDA510(K) Number		K063641
Main Technical Specifications	CO_2 Measurement Range: 0 to 150 mmHg 0 to19.7%（V/V） 0 to 20 KPa (Barometric Pressure supplied by Host) CO_2 Calculation Method: Non-dispersive infrared gas analysis CO_2 Response Time: <1second CO_2 Accuracy: 0-40 mmHg ±2 mmHg 41-70 mmHg ±5% of reading 71-100 mmHg ±8% of reading 101-150 mmHg ±10% of reading Respiration Rate Range: 3 to 150 breaths per minute (BPM) Respiration Rate Accuracy: ± 1 breath Flow rate: 50 cc/min~250cc/min Operating conditions: Temperature: 5°C ~40°C Humidity: 30%~75% Storage conditions: Temperature: -20°C~55°C Humidity: < 93%, noncondensing	SpO_2 Display: 0%~100% Pulse Rate display: 30bpm~240bpm Resolution: SpO_2: ±1 % SpO_2 Pulse Rate: ±1bpm Accuracy: SpO_2: ±3digits Pulse Rate: ±2bpm or ±2% (which ever is greater) The performance under low perfusion condition: The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%. Intended patient population: Adult patients Operating conditions: Temperature: 5°C ~40°C Humidity: ≤95% Atmospheric pressure: 70kPa~106kPa Storage conditions: Temperature: -10°C~55°C Humidity: ≤95% Atmospheric pressure: 50kPa~106kPa

The following performance testing was performed to demonstrate substantial equivalence of the subject device Capnograph and SPO2, Model Capno-H, and applicable standards:

Standard	Predicate	Capno-H	Comparison
IEC 60601-1: 1990+A1+A2+A13	Testing complete, complies	Testing complete, complies	Both the predicate and the Capno-H underwent testing to prove compliance to the General requirements for safety. Both the predicate and the submitted Capno-H complied with this standard. This demonstrates that the predicate and submitted devices are safe to operate.
IEC 60601-1-2: 2007	Testing complete, complies	Testing complete, complies	Both the predicate and the Capno-H underwent testing to show compliance for the EMC requirements in IEC 60601-1-2. Both the predicate and the submitted Capno-H complied with this standard. This demonstrates that the Capno-H and the predicate operate within the defined parameters of the IEC EMC standard.
IEC 60601-1-8: 2006	Testing complete, complies	Testing complete, complies	IEC Standard 60601-1-8 defines the basic safety and essential performance tests and guidance to show compliance for alarm systems in medical electrical equipment. Both the submitted device and predicate device complied with this standard, establishing conformity to the standard conditions.
ISO 80601-2-55	Testing complete, complies	Tested to ISO 21647: 2004; Complies	The submitted device was tested and complied with the criteria defined in ISO 80601-2-55, whereas the predicate device was tested and complied with ISO 21647:2004. Both of these standards define the basic safety and essential performance of respiratory gas monitors. Both standards define the physical construction requirements, electrical safety, alarms and measurement accuracy of a respiratory gas monitor. Both the predicate and the submitted Capno-H complied with these comparable standards, exhibiting compliance to equipment safety and performance standards.

Standard	Predicate	Capno-H	Comparison
ISO 10993-1	Testing regimen developed.	Testing regimen developed.	ISO 10993-1 defines the principles of biological evaluation, the categorization of devices according to type and duration of body contact and the selection of appropriate tests for the devices. Both the predicate and the submitted Capno-H utilized this standard to develop the testing protocols for biocompatibility testing.
ISO 10993-5	Testing complete, complies	Testing complete, complies	ISO 10993-5 defines methods of incubation of cultured cells directly or through diffusion in contact with the medical device. The methods determine the biological response of mammalian cells *in vitro* with the appropriate biological parameters. Both the predicate and submitted Capno-H underwent testing in accordance with the bounds of ISO 10993-5 and complied with the criterial in this standard. This shows the submitted device is comparable to the predicate for *in vitro* biological compatibility.
ISO 10993-10	Testing complete, complies	Testing complete, complies	ISO 10993-10 defines the assessment procedure with regards to the device's potential to produce irritation and delayed-type hypersensitivity. Both the predicate and the Capno-H underwent testing to assess the medical devices' potential to product irritation and delayed-type hypersensitivity. The Capno-H and the predicate complied with this standard. This demonstrates compliance to this biocompatibility standard and shows compliance for patient safety.
ISO 9919	Utilizes an FDA approved $SP0_2$ device	Testing complete, complies	The $SP0_2$ component of the submitted Capno-H device has been previously cleared by the FDA under K063641, which is the predicate device.
EN 61000-3-2:2006	Testing not done	Testing complete, complies	This standard is for Electromagnetic Compatibility (emc) - Part 3-2: Limits -, which tests for limits For Harmonic Current Emissions (equipment Input Current <= 16 A Per Phase)

Standard	Predicate	Capno-H	Comparison
EN 61000-3-3	Testing not done	Testing complete, complies	This standard is for Electromagnetic Compatibility (emc) - Part 3-3: Limits - , which tests for the limitation Of Voltage Changes, Voltage Fluctuations And Flicker In Public Low-voltage Supply Systems, For Equipment With Rated Current 16 A Per Phase And Not Subject To Conditional Connection
FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices	Used as guidance in development	Used as guidance in development	Guidance for the approach for development and testing of software in medical devices.
IEC 60601-1-4	Used as guidance in development. Testing performed to prove V&V.	Used as guidance in development. Testing performed to prove V&V.	This standard specifies the requirements for the process by which a programmable electrical medical system is designed.

All of the pre-determined acceptance criteria were met.

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics, and performance testing, the subject Capnograph and Oximeter, Model Capno-H has demonstrated to be substantially equivalent to the predicate Vital Signs Monitor, Model PC-900A.

END