April 30, 2026

Cosinuss GmbH
Ralph Heim
Quality Manager
Kistlerhofstrasse 60
Munich, Bavaria 81379
Germany

Re: K253436
Trade/Device Name: c-med0 alpha
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, FLL
Dated: March 31, 2026
Received: March 31, 2026

Dear Ralph Heim:

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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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.	K253436

Please provide the device trade name(s).

c-med° alpha

Please provide your Indications for Use below.

The medical purpose of the c-med° alpha device is a non-invasive measurement of body temperature (TEMP), blood oxygen saturation (SpO2) and Pulse Rate (PR). In combination with the c-med° software applications the system is indicated for spot-checking and/or continuous data collection of adults during non-motion conditions in hospitals, medical facilities and home healthcare environments. The system is intended for spot checking, meaning the sensor device can be worn continuously, but the user must actively start and open the App whenever they intend to check or collect manually the measurement data.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253436

510(k) Summary

Prepared on: 2026-04-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Cosinuss GmbH
Applicant Address	Kistlerhofstr. 60 Munich Bayern 81379 Germany
Applicant Contact Telephone	+49 89 740 418
Applicant Contact	Mr. Ralph Heim
Applicant Contact Email	zulassung@cosinuss.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	c-med° alpha
Common Name	c-med° alpha
Classification Name	Monitor, Physiological, Patient (without arrhythmia detection or alarms) Additional: Oximeter; Clinical electronic thermometer
Regulation Number	21 CFR 870.2300, 21 CFR 870.2700, 21 CFR 870.2910
Product Code(s)	MWI, DQA, FLL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212975	MedWand Device	MWI
K170047	All-in-One Health Monitor, PC-303	MWI
K233827	OxiWear	DQA

Device Description Summary

21 CFR 807.92(a)(4)

The medical purpose of the c-med° alpha device is a non-invasive measurement of body temperature (TEMP), blood oxygen saturation (SpO2) and Pulse Rate (PR). In combination with the c-med° software applications the system is indicated for spot-checking and/or continuous data collection of adults during non-motion conditions in hospitals, medical facilities and home healthcare environments. The system is intended for spot checking, meaning the sensor device can be worn continuously, but the user must actively start and open the App whenever they intend to check or collect manually the measurement data.

Part of the system are:
- c-med° alpha sensor device (in-ear wearable - silicone casing),
- c-med° App,
- Bluetooth Application Programmable Interface (API),
- cosinuss° charging box and charging adapter with USB Cable.

The measured data is sent via the Bluetooth API by the in-ear sensor device to enable data transfer, spot-checking through the App and continuous data collection.

In contrast to the common medical devices, the user only needs one device to spot-check all relevant parameters. A concrete medical indication in terms of specific diseases is not intended. The device and the App does not recommend any concrete treatment. Based on

the vital parameter measurement, it is intended to allow and simplify spot-checking and manual data collection of different physical reactions: hypothermia, hyperthermia (fever), changes in circulatory system, tachycardia and bradycardia. The medical device is especially designed to measure the vital parameters of adults. Thus, the patient population includes independent of gender, all adults under the condition that the sensing earbud fits into the auditory ear canal and the patient does not have any injuries regarding the auditory ear canal. The c-med° App is intended to be used as visualization tool, which allows live data monitoring. Live data monitoring" for c-med° alpha means on-screen, real-time display of the most recently acquired SpO_2 and pulse-rate values at 1 Hz and body-temperature values at 0.1 Hz while the sensor is properly worn and connected; if no new data are received for 30 seconds, the display clears to prevent use of outdated values.

The device does not generate physiological alarms and is not intended for active patient surveillance or automated notification of clinical deteriorationThere are no alarms and data is not modified, analyzed or interpreted by the App. The c-med° App can only be used with the sensor device (c-med° alpha). By adhering to the cosinuss° API specifications, it is possible to connect the sensor device with other systems (e.g. third party Apps) to allow data transmission for further analysis. Depending on the third party system, the c-med° alpha device can be also used for remote patient monitoring and continuous data collection (not part of the device).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The medical purpose of the c-med° alpha device is a non-invasive measurement of body temperature (TEMP), blood oxygen saturation (SpO2) and Pulse Rate (PR). In combination with the c-med° software applications the system is indicated for spot-checking and/or continuous data collection of adults during non-motion conditions in hospitals, medical facilities and home healthcare environments. The system is intended for spot checking, meaning the sensor device can be worn continuously, but the user must actively start and open the App whenever they intend to check or collect manually the measurement data.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Same: The indications of the predicate devices have more parameters, but cover the ones of the subject device (SpO2, PR, TEMP). The secondary predicate device is also intended for paediatric use, but also covers adult patients.

Technological Comparison 21 CFR 807.92(a)(6)

The table at the end of this document provides a detailed comparison between c-med° alpha and the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The c-med° alpha system has been evaluated and verified to comply with recognized standards through verification and validation testing - the following testing was performed:

Cleaning, disinfection and shelf-life:
The c-med° alpha is a reusable device. The device is not provided sterile and is not intended to be sterilized by users. The device is intended to be cleaned and disinfected between uses.
One EPA-certified commonly available disinfectant is specified in the corresponding section of the instructions for use. Its use has been validated according to ISO 17664-2 and the FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling – Guidance
for Industry and Food and Drug Administration Staff", issued March 17, 2015, and does not negatively affect the device while providing sufficient cleanliness. The product has a low probability of time-dependent degradation and is not provided sterile. Therefore, the concept of a shelf life or expiration date does not apply to the c-med° alpha Device. A use life of 2 years has been validated.

Biocompatibility:
Biocompatibility was evaluated within the risk management framework according to ISO 10993-1:2018 and the FDA's guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". All patient contacting materials were evaluated on their long-term suitability for the contact with intact skin based on literature and biological / chemical testing according to ISO 10993-5:2009 and ISO 10993-18:2020. All requirements for a safe use of the device are fulfilled. A clear rationale for applying the least burdensome approach as per Attachmet G of FDAs guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" is provided, demonstrating that further animal testing would not add value to user safety.

Software and System validation:
The c-med° alpha comprises firmware and the software c-med° which were verified and validated according to IEC 62304, IEC 81001-5-1.

Functions Software validation demonstrated that the firmware and c-med° met the software system requirements.

Cybersecurity:
Cybersecurity activities were conducted according to IEC 81001-5-1 and the FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Human Factors and Usability validation:
The overall system was validated to confirm that the device meets its intended use, i.e. can be used safe and effectively by the specified users within the specified use environment, taking into account human factors and usability requirements according to ISO 62366-1 and Guidance Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016

Electrical Safety and Electromagnetic Compatibility testing:
c-med° alpha was tested according to and is in compliance with recognized standards for electrical safety and electromagnetic compatibility. All applicable requirements of IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11 were met.

Pulse Oximetry Testing:
Testing according to ISO 80601-2-61, Pulse Oximeters - Premarket Notification Submissions [510(k)s], March 4, 2013 was conducted and passed. Moreover, Pulse Rate and Perfusion testing was performed - pulse rate and low/high perfusion conditions were simulated using a functional tester. Testing with a patient simulator verified the performance of the quality index (QI) implemented in the pulse rate algorithm and demonstrates, that the device has a level of SpO2 and Pulse Rate accuracy, under conditions of low/high perfusion, comparable to an industry standard pulse oximeter.

Medical IR-Thermometer Testing:
Testing according to ASTM E1965-98 and ISO 80601-2-56 in alignment with IEC 60601-1-12 §4.2.2 was conducted and passed. Testing demonstrated laboratory accuracy under low Temperature Environment (0°C / 32°F).

Clinical data - Pulse Oximeter:

A clinical study was conducted according to ISO 80601-2-61, FDA-2007-D-0205 and results demonstrate substantial equivalence and validation of the measurement accuracy of the pulse oximetry unit of the c-med° alpha compared to SaO2 values determined by blood gas analysis (gold standard).
In this study, the c-med ◦ alpha achieves an overall accuracy ARMS = 2.9 %. The data set contained a total of 223 data points from 17 subjects. The mean deviation (md) of the Bland-Altman calculation results in a bias of md = -0.8 %. The upper and lower limits of agreement are ULOA = 5.8 % and LLOA = -4.3 %. When dividing the data samples in groups of male or females no significant differences were found. The same applies to the evaluation after perfusion index (PI). No significant differences in ARMS were observed for the different PIs within the relevant device specific range of 0.2 to 2. The overall ARMS based on data of participants with Fitzpatrick-Scale Type V-VI (dark skin) amounts to ARMS = 3.5 % and is higher than the ARMS obtained from the measurements with participants with Fitzpatrick-Scale I-IV (ARMS = 2.3 %). Considering the ISO and FDA guidance, the ARMS of 3.5 % still remains within the acceptable limits for the subgroup of individuals with high pigmentation. With a total ARMS of 2.9 %, the c-med ◦ alpha system meets the accuracy requirements according to FDA-2007-D-0205 and ISO 80601-2-61. To ensure that the labeled performance reflects the most conservative estimate across all evaluated populations, the accuracy specification has been updated to ARMS of 3.5% over the range of 70–100% SaO_2. To ensure that the labeled performance reflects the most conservative estimate across all evaluated populations, the accuracy specification has been updated to ARMS of 3.5% over the range of 70–100% SaO_2.

Moreover, the study demonstrates continuous data collection by the c-med° alpha was completed with 100% success during the clinical setting - Throughout the entire study, all data measured by the c-med° alpha (SpO2, pulse rate, body temperature, quality index, and perfusion index) were successfully received via the cosinuss° API.

Clinical data - Medical IR-Thermometer:

A clinical study was conducted according to ASTM E1965-98, ISO 80601-2-56. The results demonstrate high measurement accuracy of the non-invasive, in-ear infrared temperature measurement with the c-med° alpha compared to the invasive measurement of the esophageal temperature (gold standard).

Clinical measurement accuracy c-med° alpha (REFERENCE BODY SITE: esophagus):
- Clinical Bias: -0.06 °C
- ARMS: 0.31 °C
- Limits of Agreement: [-0.65 °C, 0.53 °C]
- Clinical Repeatability: 0.1

Moreover, the study demonstrates continuous data collection by the c-med° alpha was completed with 100% success during the clinical

setting - Throughout the entire study, all data measured by the c-med° alpha (SpO2, pulse rate, body temperature, quality index, and perfusion index) were successfully received via the cosinuss° API.

The 510(k) Pre-market Notification contains adequate information and data to determine that the c-med° alpha system is as safe as the legally market predicate and reference device(s). None of the differences identified raise any new issues regarding safety or effectiveness. Therefore, we conclude that c-med° alpha is substantially equivalent to the primary predicate device MedWandTM as well as the secondary predicate device All-in-One Health Monitor PC-303.

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
510(k) Number	K253436	K212975	K170047	-
Device Name, Model	c-med° alpha	MedWand™ Device	All-in-One Health Monitor, PC-303	-
Manufacturer	Cosinuss GmbH	MedWand Solutions, Inc.	Shenzhen Creative Industry Co., Ltd.	-
Intended Use				
Regulation Number	21 CFR 870.2300	21 CFR 870.2300	21 CFR 870.2300	Same
Product code	MWI, FLL, DQA	MWI, DQA, DQD, FLL, ERA	MWI, DQA, DXN, FLL, NBW, DSH	Same: Product codes of the subject device are included with both predicate devices
Indications for Use	The medical purpose of the c-med° alpha device is a non-invasive measurement of body temperature (TEMP), blood oxygen saturation (SpO2) and Pulse Rate (PR). In combination with the c-med° software applications the system is indicated for spot-checking and/or continuous data collection of adults during non-motion conditions in hospitals, medical facilities and home healthcare environments. The system is intended for spot checking, meaning the sensor device can be worn continuously, but the user must actively start and open the App whenever they intend to check or collect manually the measurement data.	The MedWand™ Device, in combination with the MedWand™ Software Application installed on an attached mobile device or computing system, is an intermittent vital sign measuring and examination system intended to collect, record, and display the following information: Oxygen saturation (SpO2) Pulse rate (PR), Infrared body temperature (TEMP), Amplified auscultation sounds filtered for heart, lungs, and abdomen (STETH), Photographs of areas needing assessment (CAMERA). The device is intended for use by adult lay users independently or guided by a health care professional (HCP) in home and nonacute clinical environments. The MedWand™ Device is intended for use by trained adults only who can use smart phones, tablets, or computers proficiently. Collected information is not intended for self-diagnosis. Interpretation and assessment of results should be	The All-in-One Health Monitor PC-303 is a device designed for spot-checking measuring of the patient's physiological parameters, such as Non-Invasive Blood Pressure (NIBP), Oxygen saturation (SpO2), Pulse Rate (PR) and Body Temperature (TEMP); Additionally, the device is available to communicate with the compatible Blood Glucose Monitoring System and ECG monitor to make the measurement. This device is applicable for Adult and Pediatric (age≥3 years old) use in clinical institutions and has no conditions or factors of contraindication	Same: The indications of the predicate devices have more parameters, but cover the ones of the subject device (SpO2, PR, TEMP). The secondary predicate device is also intended for paediatric use, but also covers adult patients.

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
		performed by an HCP. Collected information can be provided to an HCP when used as a standalone device. Additionally, the MedWand™ Device can integrate with external data communications systems (not part of the MedWand™ Device) through a programming interface. This integration will facilitate interactions between the lay user and HCP for telemedicine. The device is intended for spot-checking and does not have continuous monitoring capability or alarm features		
General				
Vital Parameters	Blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. Body temperature (TEMP) by the infrared radiation energy technology.	Blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. Body temperature (TEMP) by the infrared radiation energy technology.	Blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. Non-invasive blood pressure (NIBP, the pressures of systolic, diastolic and mean) by the oscillating method and body temperature (TEMP) by the infrared radiation energy technology	Same: The Secondary Predicate Device monitors more parameters, but covers all of the subject device functions.
Patient population	Adults	Adults	Adult and Pediatric (age≥3 years old)	Same: The Secondary Predicate Device is also intended for paediatric use, but this has no influence on the safety of the subject device.
Use Environment	Home use or clinical institutions	Home use or non-acute clinic	Clinical institutions	Same to both predicate devices. Outdoor conditions are compared regarding the characteristic “Operating Temperature”
Rx or OTC	Rx	Rx	Rx	Same
Platform for software	Android / iOS tablet or smartphone	Windows based computer, laptop or Android tablet or smartphone	Integrated within the device, patients tablet or smartphone	Secondary predicate: Not specified within 510(k) summary
Power Supply	Rechargeable Lithium Battery	Supplied by the patient-supplied mobile computing platform via USB cord	Battery or AC	Same as the secondary predicate device.
Power requirement	100 – 240 VAC, 50/60 Hz; Rechargeable lithium battery, 3.7VDC	5 V, 2.0A	(100-240)VAC, 50/60Hz, 15VA; Rechargeable lithium battery, 3.7VDC	Same as the secondary predicate device.
Battery charging indicator	Available	N/A	Available	Same as the secondary predicate device.
Low battery indicator	Available	N/A	Available	Same as the secondary predicate

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
				device.
Battery charge time, typ.	Approx. 1 hour for charging	N/A	Maximum 8 hours for charging	Different: faster charging than secondary predicate device. No impact on device safety. Subject device fulfills all requirements regarding electrical safety / EMC.
Flammable anesthetics	N/A	N/A	N/A	Same
Connection	Bluetooth Smart wireless data link (USB for recharging battery only)	USB Type C cord (included)	USB Type C cord	Different: The subject device sends the captured data via Bluetooth function. This function is also utilized by the Bluetooth reference device. Subject device fulfills all requirements regarding electrical safety / EMC / FCC testing.
Work Mode	Spot-Checking: The sensor device is worn continuously and live data is displayed for spot checking.	Spot-checking	Spot-checking	Similar Unlike the predicate devices, the subject device is a wearable, which has the benefit to be worn continuously and allows live data for spot-checking. This has no impact on the device safety and is in alignment with the intended use of the reference device which is continuously worn for spot-checking (intended use: “live data monitoring” with a mobile device.
Alarm	No alarms	No alarms	No alarms	Same
Use life	2 years	3 years	Not specified within 510(k) summary	Similar to primary predicate device.
Physical dimension	55.2 mm x 58.6 mm x 10.0 mm	H x W x L: 2.40in x 2.5in x 5.00in (61 x 64	165(L) X 96(W) X 68mm(H)	Different: The subject device is

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
(mm)		x 127mm)		considerably smaller. This has no impact on the device safety.
Weight (kg)	9g	5.75oz (163g)	440g	Different: The subject device is considerably lighter. This has no impact on the device safety.
Display	Display on patient-supplied mobile computing platform (tablet, smartphone)	Display on patient-supplied mobile computing platform (computer, laptop, tablet, smartphone)	4.3" Segment LCD	Same as the primary predicate device.
Type, Degree of protections against electric shock	Type BF applied part	Type BF applied part	Type BF applied part	Same
Operating Temperature	Continuous Operating Conditions: 5 °C – 40 °C (32°F to 104°F)	61°F to 104°F (16°C to 40°C)	5℃ ~ 40℃	Same as the secondary predicate device. All devices have a comparable range, no impact on device safety. Moreover, bench tests at different ambient transient operating conditions 0 °C – 50 °C (32°F to 122°F) are conducted and requirements are fulfilled.
Operating RH	15% to 95% non-condensing	20% to 95% non-condensing	30% ~ 80%, noncondensing	Similar: All devices have a comparable range, no impact on device safety
Atmospheric pressure	700-1060 hPa	Sea level to at least 3,000 m (˜10,000 ft)	70.0kPa~106.0kPa	Same: Atmospheric pressure at 3000m is about 700 hPa
Storage Temperature	-25 °C – 70 °C (-13°F to 158°F)	-4°F to 122°F (-20°C to 50°C)	-20℃~60℃	Similar: All devices have a comparable range, no impact on device safety
Storage RH	0% to 95% non-condensing	5% to 95% non-condensing	10%~95%, noncondensing	Similar: All devices have a comparable range, no impact on device safety
Splash/Water/ Dust Ingress	IP22 (charging box) and IP47 (sensor) under IEC 60529	IP22 under IEC 60529	Not specified within 510(k) summary	Similar: The subject device fulfils all requirements regarding electrical safety.
Electric Safety & EMC Standard Applied	ANSI/AAMI/IEC 60601-1:2005 +C1:2006 +C2:2007+A1:2012 IEC 60601-1-2:2014	ANSI/AAMI/IEC 60601-1:2005 +C1:2006 +C2:2007+A1:2012 IEC 60601-1-2:2014	IEC60601-1:1988 A1:1991,+ A2:1995 IEC 60601-1- 1:2000 IEC60601-1- 2:2007	Same as the primary predicate device

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
	IEC 60601-1-11:2015	IEC 60601-1-11:2015	IEC 60601-1-4	
Pulse oximetry				
Scientific Principle	Detection of light collected from LEDs of varying wavelengths through blood to measure blood oxygen saturation based on amount of light absorbed by hemoglobin in the blood.	Detection of light collected from LEDs of varying wavelengths through blood to measure blood oxygen saturation based on amount of light absorbed by hemoglobin in the blood.	Detection of light collected from LEDs of varying wavelengths through blood to measure blood oxygen saturation based on amount of light absorbed by hemoglobin in the blood.	Same
Sensor geometry	Reflectance	Reflectance	Creative SpO2 module with the same principle as PC-60(K063641) Creative SpO2 sensor only	Same as the primary predicate device.
SpO2 measurement range & accuracy	±3% (during 70%-100%)	Displayed range: 70%~100% ±2% (during 90~100%), ±3% (during 70~89%)	Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)	Similar: The subject device has a comparable accuracy as both predicate devices. It fulfils the requirements of ISO 80601-2-61.
Pulse rate measurement range	40 to 220 bpm	25 to 200 bpm	30 bpm-240 bpm	Similar: Range is covered by both the primary and secondary predicate device.
Measuring site	Ear	Body surface	Fingertip	Different: The subject device measures SpO2 in the ear canal. However, the clinical study proved that the results from the subject device meet the accuracy requirements according to FDA-2007-D-0205 and ISO 80601-2-61. All requirements regarding biological and electrical safety are met. No additional concerns

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
				regarding safety and effectiveness are raised.
Pulse rate accuracy	± 2 bpm	± 2 bpm or ± 2% (whichever is greater)	±2bpm or ±2% (whichever is greater)	Similar: The subject device has an accuracy within the same range as the primary and secondary predicate device. Accuracy is based on patient simulator data. All requirements regarding usability and clinical safety are met.
Particular Standard	ISO 80601-2-61:2017	ISO 80601-2-61:2017	ISO80601-2- 61 SpO2	Same
Thermometer				
Scientific principle	Non-contact infrared technology	Non-contact infrared technology	Infrared technology	Same
Measuring site	Ear	Forehead skin over temporal artery	Ear	Same as the secondary predicate device.
Reference Body site	Oesophagus	Rectum	Not specified within 510(k) summary	Different Reference Body Site. The device was validated against the stated reference body site and all requirements are met. No additional concerns regarding safety and effectiveness are raised.
Operating mode	Adjusted Mode	Adjusted mode: Device automatically converts surface IR temp to predicted body temp	Adjusted Mode	Same
Unit of Measurement	℃ or ℉	°C or °F	℃ or ℉	Same

Characteristic	Subject Device	Primary predicate device	Secondary Predicate Device	Similar / Different
Temperature resolution	0.1°F or °C	0.1°F or °C	0.1°F or °C	Same
Temperature measurement range (body)	34.0°C – 43.0°C (93.2 – 109.4°F)	93°F~107.6°F (33.9°C ~42.0°C)	32.0℃ to 43.0℃ (90℉ to 109.5℉)	Same
Temperature measurement accuracy	± 0.3 °C (± 0.5 °F) within 34.0 – 35.0 °C (93.2 – 95 °F) ± 0.2 °C (± 0.4 °F) within 35.0 – 42.0 °C (95 – 107.6 °F) ± 0.3 °C (± 0.5 °F) within 42.0 – 43.0 °C (107.6 – 109.4 °F)	± 0.5°F (± 0.3°C)	±0.2℃ (36.0℃ to 39.0℃), ±0.3℃ (the rest); ±0.4℉ (96.8℉ to 102.2℉), ±0.5℉ (the rest)	Same
Particular Standard Applied	ISO 80601-2-56:2017 and ASTM E1965:1998(2016)	ISO 80601-2-56:2017	ASTM E1965:1998(2009)	Same
Biological safety				
Materials	Patient & user contact surfaces: Silicone and coloring agents	Patient & user contact surfaces: polycarbonate/polycarbonate-polybutylene terephthalate blend	Not specified within 510(k) summary	Different: All requirements for biological safety are fulfilled for the subject device.
Particular standards	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-18:2020	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993- 10:2010	Different: All requirements for biological safety are fulfilled for the subject device.
Cleaning/ Disinfection	Clean/disinfect between uses (commonly available agent recommended)	Clean/disinfect between uses and patients. (4 commonly available agents recommended)	Recommended on a regular basis	Same as the primary predicate device
Sterility	Non-sterile and not intended to be sterilized	Non-sterile and not intended to be sterilized	Non-sterile and not intended to be sterilized	Same

Table 1: Basic Device Characteristics – Comparison with Predicate Device