June 12, 2022

Taiwan Aulisa Medical Devices Technologies, Inc.
% Don Mizota
Consultant
Don Mizota
725 Morninghome Road
Danville, California 94526

Re: K203208
Trade/Device Name: Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, FLL, DRG
Dated: June 7, 2022
Received: June 9, 2022

Dear Don Mizota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203208

Device Name
Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System

Indications for Use *(Describe)*

GA2000

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2000) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.

GA2001

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2001) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions.

GA2002

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2002) is indicated for use in measuring, recording, and displaying body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

GA2100

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2100) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

GA2101

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2101) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Assigned 510(k) number: K203208

5.1 General Information

Date of Preparation	June 10, 2022
Company Identification	Taiwan Aulisa Medical Devices Technologies, Inc. Rm. 1052, Bldg. H, 10F., No.3-2, YuanQu St., Nangang Dist., Taipei City 115 TW TEL.: +886-2-2655-7297 FAX: +886-2-2655-7260
Contact Person	Paul Liu Regulatory Affairs Manager Taiwan Aulisa Medical Devices Technologies, Inc. Email: paul.liu@aulisa.com

5.2 Trade/Device Name

Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System

5.3 Regulatory Information

Regulation Number	Product Code	Classification Name	Device Class
870.2700	DQA	Oximeter	Class II
880.2910	FLL	Clinical electronic thermometer	Class II
870.2910	DRG	Radiofrequency Physiological Signal Transmitter and Receiver	Class II

5.4 Predicate Device(s)

Primary predicate

- K183067, Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.

Secondary predicate

- K191207, Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.
- K181013, Fever Scout™ Continuous Monitoring Thermometer, VivaLnk Inc.

5.5 Device Description

The subject device is a digital vital sign monitoring system that measures and displays a patient's vital signs, i.e. pulse rate, oxygen saturation (SpO2) and body temperature. It is also equipped with an audio/video camera to monitor the patient in real time. In addition, the subject device provides visual and auditory alarms that alert the caregiver when a patient's vital signs fall outside of pre-set limits or when a technical error is detected. During a physiological alarm event, the vital sign data along with the audio/video data are recorded automatically by the subject device. The caregiver can review the historical data whenever needed.

The sensor module(s) of the subject device detects vital signs and sends out the data to the Receiver/Transponder using Bluetooth technology. The Receiver/Transponder then transmits, via a customer Wi-Fi network, the physiological data along with audio/video signals obtained by an embedded camera to an Aulisa-supplied tablet (i.e. the Display Unit).

The subject device contains a total of three Aulisa sensor modules, Adult/Pediatric Oximeter Module, Infant Oximeter Module, and Thermometer Module. The three Aulisa sensor modules connect to the Receiver/Transponder either independently or simultaneously, resulting in five system configurations and system model names as listed below.

System Model	Aulisa Sensor Module(s)	Population	Parameters
GA2000	Adult/Pediatric Oximeter Module	• Adult (> 40 kg / 88 lbs) • Pediatric (10 kg – 40 kg / 22 lbs – 88 lbs)	• SpO2 • Pulse Rate
GA2001	Infant Oximeter Module	• Pediatric & Infant (< 10 kg / 22 lbs)	• SpO2 • Pulse Rate
GA2002	Thermometer Module	• Adult • Pediatric • Infant	Body Temperature
GA2100	• Adult/Pediatric Oximeter Module • Thermometer Module	• Adult • Pediatric	• SpO2 • Pulse Rate • Body Temperature
GA2101	• Infant Oximeter Module • Thermometer Module	• Pediatric & Infant	• SpO2 • Pulse Rate • Body Temperature

5.6 Intended Use

GA2000

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2000) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.

GA2001

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2001) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions.

GA2002

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2002) is indicated for use in measuring, recording, and displaying body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

GA2100

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2100) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

GA2101

The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2101) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions.

The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.

5.7 Comparison with Predicate Device

Among the system components of the subject device, the Display Unit, Receiver/Transponder, Adult/Pediatric Oximeter Module with reusable sensors, and Infant Oximeter Module have been cleared through previous Premarket Notification 510(k) submissions under Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System (K183067) and Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System (K191207), which are the predicates in this submission.

Built upon the existing configuration, a few modifications have been made 1) to include a new sensor module, the Thermometer Module, adding the body temperature feature to the subject device, and 2) to provide an alternative sensor, a disposable sensor, to the existing reusable sensors for Adult/Pediatric Oximeter Module.

Table 5.7.1 lists the similarities and differences between the subject device, by model, and primary predicate, Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System (K183067), and between the subject device and secondary predicates (K191207 and K181013).

Table 5.7.1

	Subject Device					Primary Predicate	Secondary Predicate	Secondary Predicate
Device name	Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System					Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System	Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System	Fever Scout™ Continuous Monitoring Thermometer
K number	-					K183067	K191207	K181013
Model number	GA2000	GA2001	GA2002	GA2100	GA2101	GA2000	GA2001	-
Indications for use	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2000) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities,	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2001) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities,	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2002) is indicated for use in measuring, recording, and displaying body temperature. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2100) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals,	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2101) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals,	The Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and audio video signals of adult and	The Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is indicated for spot-checking and/or	The wireless Fever Scout™ Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and a non-invasive and single patient use in the hospital. This product is intended for non-urgent ambulatory continuous armpit body temperature

	Subject Device					Primary Predicate	Secondary Predicate	Secondary Predicate
	home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.	home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions.	The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.	medical facilities, home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions. The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.	medical facilities, home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well-perfused conditions. The Thermometer Module is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants.	pediatric patients. It is indicated for spot-checking and/or continuous monitoring of patients during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.	continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.	monitoring from ages 29 days and older.
Patient population	adult, pediatric	pediatric, infant	adult, pediatric, infant	adult, pediatric, infant	adult, pediatric, infant	adult, pediatric	pediatric, infant	ages 29 days and older

	Subject Device					Primary Predicate	Secondary Predicate	Secondary Predicate
Use environment	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	hospitals, medical facilities, home care, subacute environments	home, hospital
Measurement	Pulse rate, SpO2	Pulse rate, SpO2	body temperature	Pulse rate, SpO2, body temperature	Pulse rate, SpO2, body temperature	Pulse rate, SpO2	Pulse rate, SpO2	body temperature
Disposable or reusable	reusable/ disposable	reusable/ disposable	reusable/ disposable	reusable/ disposable	reusable/ disposable	reusable	reusable	reusable/ disposable
Wireless communication	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	Bluetooth 4.0 Wi-Fi	• Bluetooth BLE • Wireless (Wi-Fi) 2.4G
Operating platform	Aulisa Display Unit	Aulisa Display Unit	Aulisa Display Unit	Aulisa Display Unit	Aulisa Display Unit	Aulisa Display Unit	Aulisa Display Unit	• iPhone 5S+ or later & iOS 8.0 or later • Android 4.3 or later
Alarms	Visual and auditory alarms	Visual and auditory alarms	Visual and auditory alarms	Visual and auditory alarms	Visual and auditory alarms	Visual and auditory alarms	Visual and auditory alarms	na
Real-time audio/video	Yes	Yes	Yes	Yes	Yes	Yes	Yes	na
Pulse Oximetry								
Measuring site	Finger	Foot	na	Finger	Foot	Finger	Finger	na
Out-of-hospital transport	No	No	na	No	No	No	No	na
Motion	Non-motion	Non-motion	na	Non-motion	Non-motion	Non-motion	Non-motion	na
Perfusion	Well-perfused	Well-perfused	na	Well-perfused	Well-perfused	Well-perfused	Well-perfused	na

	Subject Device					Primary Predicate	Secondary Predicate	Secondary Predicate
Technology	Red and Infrared technology	Red and Infrared technology	na	Red and Infrared technology	Red and Infrared technology	Red and Infrared technology	Red and Infrared technology	na
Wavelengths & output power	Red: 660 nm @ 1.8 mw	Red: 660 nm @ 9.8 mw	na	Red: 660 nm @ 1.8 mw	Red: 660 nm @ 9.8 mw	Red: 660 nm @ 1.8 mw	Red: 660 nm @ 9.8 mw	na
	Infrared: 905 nm @ 2 mw	Infrared: 880 nm @ 6.5 mw		Infrared: 905 nm @ 2 mw	Infrared: 880 nm @ 6.5 mw	Infrared: 905 nm @ 2 mw	Infrared: 880 nm @ 6.5 mw	na
Measurement accuracy (No motion)	SpO_2: ± 3 digits (70-100%)	SpO_2: ± 3 digits (70-100%)	na	SpO_2: ± 3 digits (70-100%)	SpO_2: ± 3 digits (70-100%)	SpO_2: ± 3 digits (70-100%)	SpO_2: ± 3 digits (70-100%)	na
	PR: ± 3% (30-290 bpm)	PR: ± 3 digits (18-300 bpm)		PR: ± 3% (30-290 bpm)	PR: ± 3 digits (18-300 bpm)	PR: ± 3% (30-290 bpm)	PR: ± 3 digits (18-300 bpm)	na
Displayed range	SpO_2: 1-100% PR: 30-290 bpm	SpO_2: 0-100% PR: 18-300 bpm	na	SpO_2: 1-100% PR: 30-290 bpm	SpO_2: 0-100% PR: 18-300 bpm	SpO_2: 1-100% PR: 30-290 bpm	SpO_2: 0-100% PR: 18-300 bpm	na
Power supply	Lithium battery AC adaptor	Lithium battery AC adaptor	na	Lithium battery AC adaptor	Lithium battery AC adaptor	Lithium battery AC adaptor	Lithium battery AC adaptor	na
Body Temperature								
Measurement accuracy	na	na	89.6°F-107.6°F: ±0.2°F (32°C-42°C: ±0.1°C)	89.6°F-107.6°F: ±0.2°F (32°C-42°C: ±0.1°C)	89.6°F-107.6°F: ±0.2°F (32°C-42°C: ±0.1°C)	na	na	98.6°F-102.2°F: ±0.2°F (37°C-39°C: ±0.1°C) 95°F-98.6°F: ±0.4°F (35°C-37°C: ±0.2°C)

	Subject Device					Primary Predicate	Secondary Predicate	Secondary Predicate
								102.2°F-107.6°F: ±0.4°F (39°C-42°C: ±0.2°C)
Display range	na	na	89.6°F-107.6°F (32°C-42°C) <89.6°F (32.0°C) displays "Lo" >107.6°F (42.0°C) displays "Hi"	89.6°F-107.6°F (32°C-42°C) <89.6°F (32.0°C) displays "Lo" >107.6°F (42.0°C) displays "Hi"	89.6°F-107.6°F (32°C-42°C) <89.6°F (32.0°C) displays "Lo" >107.6°F (42.0°C) displays "Hi"	na	na	95°F-107.6°F (35°C-42°C)
Operation mode	na	na	Continuous	Continuous	Continuous	na	na	Continuous
Measuring site	na	na	Axillary (armpit)	Axillary (armpit)	Axillary (armpit)	na	na	Axillary (armpit)
Power supply	na	na	CR2025	CR2025	CR2025	na	na	MS Lithium rechargeable battery 3.0V
Duration of continuous patch use	na	na	up to 24 hours	up to 24 hours	up to 24 hours	na	na	7 days

5.8 Summary of Non-clinical Testing

The results of the testing demonstrate equivalence with the predicate device(s) and compliance with recognized standards. Below table summarizes test results for the subject device, which met the relevant requirements of the applicable recognized standards or claimed specifications.

Item	Reference	Result
Electrical Safety	IEC 60601-1 IEC 60601-1-11	Pass
Temperature and Humidity	IEC 60601-1	Pass
Atmospheric Pressure (Altitude)	IEC 60601-1	Pass
Defibrillation Protection	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Performance	ISO 80601-2-61 ASTM E1112 IEC 60601-1-8 IEC 60086 series	Pass
Mechanical Durability	IEC 60601-1 IEC 60601-1-11	Pass
Biocompatibility	ISO 10993-5 ISO 10993-10	Pass
Software V&V	FDA Guidance	Pass
Bench testing for Accuracy	Manufacturer's specifications	Pass
Security Testing	-	Pass
Wireless Coexistence Testing	ANSI C63.27	Pass
Durability and Performance testing	Manufacturer's specifications	Pass
CR2025 Battery Life Testing	Manufacturer's specifications	Pass

5.9 Summary of Clinical Testing

The functional oxygen saturation (SpO_2) measurements of the subject device were validated in accordance with ISO 80601-2-61. The clinical evaluation for SpO_2 accuracy was conducted on healthy male and female, light to dark skinned subjects. The SpO_2 accuracy data were calculated using the root-mean-square (A_{rms}) and the results which indicated that the subject device had an A_{rms} less than 3 digits during steady-state conditions over the range of 70-100% were in compliance with the specified performance claimed by the manufacturer.

The output temperature of the subject device is derived directly from input signal without any adjustment, and therefore no clinical validation is needed.

5.10 Conclusion

The data provided as part of this submission for the subject device supports the substantial equivalence determination.