DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 17, 2016

Midmark Corporation
Ms. Maria Moreno
Manager, Quality Management System
690 Knox Street, Suite 100
Torrance, California 90502

Re: K161909
Trade/Device Name: IQvitals Zone; Models: 1-200-0310, 1-200-0320, 1-200-0330, 1-200-0340, 1-200-0350, 1-200-0360
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, DQA, FLL
Dated: September 30, 2016
Received: October 11, 2016

Dear Ms. Maria Moreno,

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.

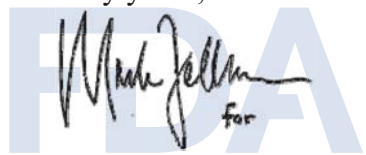
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161909

Device Name
IQvitals Zone
Models: 1-200-0310, 1-200-0320, 1-200-0330, 1-200-0340, 1-200-0350, 1-200-0360

Indications for Use *(Describe)*
The IQvitals Zone is intended to be used by clinicians and medically qualified personnel for measuring and monitoring:
- Noninvasive blood pressure for adult and pediatric patients (3 years and above)
- Pulse rate for adult and pediatric patients
- Noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2) for adult and pediatric patients
- Body temperature measured at Temporal Artery for adult and pediatric patients

The most likely location for IQvitals Zone device to be used is for monitoring patient in general medical locations, hospitals and alternative care environments.

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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SECTION 5

510(k) Summary

1. Sponsor

Midmark Corporation
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Contact: Mr. Asad Abu-Tarif; Vice President (R&D)
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Alternate Contact: Ms. Maria Moreno; Manager (Quality)
Email: mmoreno@midmark.com

Summary Preparation Date: July 7, 2016

2. Device

Trade Name	IQvitals Zone
Models	1-200-0310, 1-200-0320, 1-200-0330, 1-200-0340, 1-200-0350, 1-200-0360
Common Name	Patient Physiological Monitor
Classification	Class II
Product Code	MWI
Regulation Number	21 CFR 870.2300
Review Panel	Cardiovascular

3. Predicate Device

- Midmark Diagnostics IQmark Vital Signs Monitor (K072516)
- Vital Signs Monitor VSM 6000 Series; (K101445)
- Nellcor OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and OxiMax Sensors and Cables (K060576)
- Masimo Radical 7 Pulse CO-Oximeter and Accessories (K110028)
- Exergen TemporalScanner Thermometer (K011291)

4. Device Description

The IQvitals Zone is designed to be used for measuring and monitoring systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO2) for adult and pediatric patients. All functions of the device are performed via the touch screen display, except the power on/off function, which is a separate button on the back of the device.

The IQvitals Zone can be wirelessly connected with low energy Bluetooth to mobile computers or be connected with a USB cable to computers and has the ability to send the measurement results to the computers.

The device has a rechargeable lithium ion battery and two mounting options: a mobile cart and a wall mount. All vitals parameters can be simultaneously measured and easily viewed on the touch screen display or the connected computer. Temperature is measured at Temporal Artery and the Temperature Probe is connected serially to the IQvitals Zone.

The IQvitals Zone is offered in following models:

Device Model Configurations	**Features**				
	Non-invasive Blood Pressure Monitor Module	**Exergen Temporal Thermometer Module**	**Nellcor SpO_2 Module**	**Masimo SpO_2 Module**	**Alarms & Wireless**
1-200-0310	X	X	---	---	---
1-200-0320	X	X	X	---	---
1-200-0330	X	X	---	X	---
1-200-0340	X	X	---	---	X
1-200-0350	X	X	X	---	X
1-200-0360	X	X	---	X	X

5. Indications for Use

The IQvitals Zone is intended to be used by clinicians and medically qualified personnel for measuring and monitoring:

- Noninvasive blood pressure for adult and pediatric patients (3 years and above)
- Pulse rate for adult and pediatric patients
- Noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2) for adult and pediatric patients
- Body temperature measured at Temporal Artery for adult and pediatric patients

The most likely location for IQvitals Zone device to be used is for monitoring patient in general medical locations, hospitals and alternative care environments.

6. Technological Characteristics and Substantial Equivalence

The proposed 'IQvitals Zone' is substantially equivalent to the referenced predicate devices in regard to the intended use, fundamental scientific technology, design, and technological characteristics, as outlined in the following table:

Table 1: Substantial Equivalence Comparison between IQvitals Zone and Predicate Devices - K072516, K1010445

Characteristic	Subject Device	Predicate Devices	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Submitter	Midmark Corporation	Midmark Diagnostics Group	Welch Allyn, Inc.
Classification	Device Class: 2 Product Code: MWI 21 CFR 870.2300	Device Class: 2 Product Code: MWI 21 CFR 870.2300	Device Class: 2 Product Code: MWI 21 CFR 870.2300
Indications for Use	The IQVitals Zone is intended to be used by clinicians and medically qualified personnel for measuring and monitoring: • Noninvasive blood pressure for adult and pediatric patients (3 years and above) • Pulse rate for adult and pediatric patients • Noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2) for adult and pediatric patients • Body temperature measured at Temporal Artery for adult and pediatric patients The most likely location for IQvitals Zone device to be used is for monitoring patient in general medical locations, hospitals and alternative care environments.	The Midmark Diagnostics IQmark Vital Signs Monitor is intended to be used by clinicians and medically qualified personnel for monitoring adult, pediatric and neonatal patients for noninvasive blood pressure, pulse rate noninvasive functional oxygen saturation of arteriolar hemoglobin (Sp0 2), and body temperature. In adults and pediatric patients, temperature is monitored orally, rectally, or at axillary sites. In neonates (to 1 month) temperature is monitored at axillary sites only. The most likely locations for patients to be monitored are general medical locations, hospitals, and alternative care environments.	The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. This product is available for sale only upon the order of a physician or licensed health care professional.
Prescription / Over-The-Counter (OTC) Use	Prescription	Prescription	Prescription

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Device Design (components and parts)	The IQvitals Zone includes Midmark NIBP module, Masimo or Nellcor OEM SPO_2 module, and Exergen temporal thermometer. The Midmark NIBP module uses oscillometric blood pressure estimation algorithm to estimate patient's systolic, diastolic and mean arterial blood pressure. The SPO_2 module is Masimo Radical 7 or Nellcor NELL-1. The Main Board is the center controller for the IQvitals Zone. Internally it communicates with Wireless Board, NIBP Board, SPO_2 module, Display Board, with UART (Universal Asynchronous Receiver/Transmitter) interface. It also provides RS232 interfaces for Exergen temporal thermometer and compatible scales like Midmark's IQscale or Fairbanks scale. The Alarm Module is controlled directly by the IO ports on the Main Board. The IQvitals Zone can communicate with a laptop/PC through a USB 2.0 compliant full speed port and/or a low energy Bluetooth wireless interface. The device has a LCD touch screen that provides graphical user interface to operate the device.	The IQmark Vital Signs Monitor includes CAS Med OEM NIBP module, Masimo OEM SPO_2 module, and Midmark predictive temperature module. The CAS Med NIBP modules uses oscillometric blood pressure estimation algorithm to estimate patient's systolic, diastolic and mean arterial blood pressure. The SPO_2 module is Masimo's MS-11. The Midmark thermometer is a predictive temperature module. All modules are interfaced to the main board through UART ports. The IQmark Vital Signs Monitor can communicate with the laptop/PC through a USB 1.1 port and /or an Inferred wireless port. The device uses numerical LED display and buttons to control the device operation.	The Welch Allyn VSM 6000 Series Device incorporates Oscillometric Blood Pressure Measurement (BP) module, thermometer and SPO_2 modules A power button is located on the side of the device. A LCD with a touch screen is prominent on the front of the device and provides the primary interface for the user to interact with the device. Internal and external communications is primarily by USB. A user accessible client USB connection for data transfer is on the side of the device.

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Accessories & Peripheral Devices	• SpO2 Sensors and cables • Temperature Probes • Temperature Probe Covers • Blood Pressure Hose • Blood Pressure Cuffs • AC Power Adapter • Lithium ion battery • USB Cable • Mobile Cart for IQvitals Zone • IQvitals® Zone™ Wall Mount Articulating Arm • 15" Laptop Tray • 12" Tablet Tray	• SPO2 sensors and cables • Temperature Probes • Temperature Probe Covers • Temperature calibration key • Blood Pressure Hose • Blood Pressure Cuffs • AC Power Adapter • Lead acid battery • USB cable	• SPO2 sensors and cables • Temperature Probes • Temperature Probe Covers • Temperature calibration key • Blood Pressure Hose • Blood Pressure Cuffs • Lithium ion battery
Available Module Configurations	Noninvasive Blood Pressure (NIBP) Pulse Oximeter Temperature	Noninvasive Blood Pressure (NIBP) Pulse Oximeter Temperature	Noninvasive Blood Pressure (NIBP) Pulse Oximeter Temperature
Device Operational Modes	Adult, Pediatric	Adult, Neonatal	Adult, Pediatric, Neonatal
Noninvasive Blood Pressure (NIBP) Monitor Module Specifications			
• Operating Principle / Measurement Method	Oscillometric	Oscillometric	Oscillometric
• NIBP Modes and Range	<u>Adult Mode</u> Systolic: 50-260 mmHg Mean: 30-230 mmHg Diastolic: 20-210 mmHg <u>Pediatric Mode</u> Systolic: 50-260 mmHg Mean: 30-230 mmHg Diastolic: 20-210 mmHg	<u>Adult Mode</u> Systolic: 30-255mmHg Mean: 20-235 mmHg Diastolic: 15-220 mmHg <u>Neonate Mode:</u> Systolic: 30-135mmHg Mean: 20-125mmHg Diastolic: 15-110mmHg	<u>Adult Mode</u> Systolic: 30-260 mmHg Mean: 280 mmHg Diastolic: 20-220 mmHg <u>Pediatric Mode</u> Systolic: 30-260 mmHg Mean: 280 mmHg Diastolic: 20-220 mmHg <u>Neonate Mode</u> Systolic: 20 to 120 mmHg Mean: 130 mmHg Diastolic: 10-110 mmHg

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
• Measurement Accuracy	+/- 5 mmHg (standard deviation < 8 mmHg) *Meets ANSI.AAMI SP10:2002 standard accuracy range*	+/- 5 mmHg (standard deviation < 8 mmHg) *Meets ANSI.AAMI SP10:2002 standard accuracy range*	±5 mmHg (standard deviation < 8 mmHg) *Meets ANSI.AAMI SP10:2002 standard accuracy range*
• Measurement Resolution	1 mmHg	1 mmHg	1 mmHg
• Pulse Rate Range	40 – 200 BPM	30 – 240 BPM	30 – 200 BPM (adult, pediatric) 35 – 220 BPM (neonate)
• Pulse Rate Accuracy	±3 bpm or ±5%, whichever is greater	± 2 bpm or ± 2%, whichever is greater	±3 bpm or ±5%, whichever is greater
• Pulse Rate Resolution	1 bpm	1 bpm	1 bpm
• Initial Cuff Pressure	Automatic or User-selectable	User-selectable	Automatic
• Maximum Cuff Pressure	280 ± 5 mmHg	290 mmHg (adult mode) 145 mmHg (neonatal mode)	280 mmHg (adult, pediatric) 130 mmHg (neonate)
• Overpressure Cutoff	300 ± 30 mmHg	Adult Mode: 290 mmHg Neonatal Mode: 145 mmHg	300 mmHg ±15 mmHg (adult, pediatric) 150 mmHg maximum (neonate)
• Cuff Types	Reusable and single use cuffs	Single Use and Reusable	Single Use and Reusable
• Cuff Sizes	– Child – Small Adult – Adult – Adult Long – Large Adult – Large Adult Long – Thigh	– Infant – Neonatal – Adult	– Infant – Small Child – Child – Small Adult – Adult – Large Adult – Thigh – Neonatal

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Pulse Oximetery Specifications			
• Pulse Oximeter	• Masimo MX-5 OEM board *(previously cleared as part of Masimo Radical 7 Pulse CO-Oximeter and Accessories, under K110028)* • Nellcor NELL-1 *(previously cleared as part of OxiMax™ N-600x™ Pulse Oximeter, under K060576)*	Masimo OEM MS-11 Module	Welch Allyn NIBP module
• SpO_2 Modes	Continuous Monitoring and Off	Continuous Monitoring and Off	Continuous Monitoring and Off
• SpO_2 Sensor Types	Reusable and Disposable	Reusable and Disposable	Reusable and Disposable
• SpO_2 Sensor sizes	Adult, Pediatric	Adult, Infant and Neonatal	Adult, Infant and Neonatal
• SpO_2 Measurement Range	0-100%	0-100%	1 to 100%
• SpO_2 Measurement Accuracy	Adult: 70 - 100% (± 2%) Pediatric: 70 - 100% (± 3%)	Adult: 70 - 100% (± 2%) Neonate: 70 - 100% (± 3%)	Adult: 70 - 100% (± 2%) Pediatric, Neonate: 70 - 100% (± 3%)
• Pulse Rate Measurement Range	20 - 240 BPM (Nellcor NELL-1) 25 - 240 BPM (Masimo)	25 - 240 BPM	20-250 BPM (Nellcor) 25-240 BPM (Masimo)
• Pulse Rate Measurement Accuracy	± 3 BPM (no motion) ± 5 BPM (with motion)	± 3 BPM	± 3 BPM
• SpO_2 / Pulse Rate Resolution	SpO_2: 1% Pulse Rate: 1 bpm	SpO_2: 1% Pulse Rate: 1 bpm	SpO_2: 1% Pulse Rate: 1 bpm

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Thermometer Specifications			
• Thermometer	Exergen Temporal Scanner *(previously cleared under K011291)*	Midmark thermometer	Welch Allyn SureTemp
• Type	Temporal	Oral, Axillary, and Rectal	Oral, Axillary, and Rectal
• Measurement Range	15.5°C to 43°C (61°F to 110°F)	28.9°C to 42.2°C (84°F to 108°F)	20°C to 42.2°C (68°F to 108°F)
• Measurement Accuracy *[within the +/- 0.6°C (+- 1.0°F) range specified by ASTM E1112 standard]*	+/-0.1°C (+/- 0.2°F)	±0.1°C (±0.2°F)	±0.2°C (±0.4°F) *for temperatures ranging from 95.9°F to 107.6°F (35. 5°C to 42°C)* ±0.25°C (±0.5°F) *for temperatures outside of this range*
• Resolution	0.1 °C / 0.1 °F	0.1 °C / 0.1 °F	0.1 °C / 0.1 °F
• Response Time	~0.04 seconds	15 seconds	Not specified
Other Specifications			
Alarm Conditions	High priority: NIBP systolic, MAP, diastolic high or low; SPO2 high or low, and some high priority technical alarms Medium priority: SPO2 high or low; pulse rate high or low, and some medium priority technical alarms Low priority: Temperature high or low, and some low priority technical alarms.	Pulse rate, systolic and Diastolic BP, MAP and SpO2; high and low alarms	High priority: NIBP, SpO2, SpHb limit exceeded, and some technical alarms Medium priority: Pulse rate limit exceeded, and some technical alarms Low priority: Temperature limit exceeded and some technical alarms
Product Weight	3.9 lbs (1.77 kg)	Not specified	9.5 lbs (4.31 kg)

Characteristic	**Subject Device**	**Predicate Devices**	
	IQvitals Zone Wireless	**Midmark Diagnostics IQmark Vital Signs Monitor (K072516)**	**Vital Signs Monitor VSM 6000 Series; (K101445)**
Dimensions	10.5” x 4” x 7” (LxWxH)	Not specified	10x11x6 (HXWXD)
Power Supply	100-240 VAC, 50-60 Hz OR Lithium Ion Battery (7.2V)	100-240 VAC, 50-60 Hz OR Charged sealed lead acid battery	100-240 VAC, 50 - 60 Hz OR Lithium Ion Battery
Environmental Conditions			
Temperature (Operating)	10°C to 40°C (50°F to 104°F)	10°C to 40°C (50°F to 104°F)	10°C to 40°C (50°F to 104°F)
Humidity (Operating)	15-90% RH (non-condensing)	15-90% RH (non-condensing)	15-95% RH (non-condensing)
Altitude (Operating)	Up to 10,000 feet	Up to 10,000 feet	-557 to 10,000 feet
Temperature (Storage)	-20°C to 50°C (-4°F to 122°F)	-20°C to 65°C (-4°F to 149°F)	-20°C to 50°C (-4°F to 122°F)
Humidity (Storage)	15-95% RH (non-condensing)	15-95% RH (non-condensing)	15-95% RH (non-condensing)
Altitude (Storage)	Up to 40,000 feet	Up to 40,000 feet	Not specified

Table 2: Substantial Equivalence Comparison between IQvitals Zone and K060576

Characteristic	**Subject Device**	**Predicate Device**
	IQvitals Zone Wireless	**OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and OxiMax Sensors and Cables (K060576)**
Pulse Oximeter Module	Nellcor NELL-1	Nellcor NELL-1
SpO_2 Modes	Continuous Monitoring and Off	Continuous Monitoring and Off
SpO_2 Sensor Types	Reusable and Disposable	Reusable and Disposable
SpO_2 Sensor sizes	Adult, Pediatric	Adult, Pediatric

Characteristic	Subject Device	Predicate Device
	IQvitals Zone Wireless	**OxiMax Pulse Oximetry System with N-600x Pulse Oximeter and OxiMax Sensors and Cables (K060576)**
SpO_2 Measurement Range	0-100%	0-100%
SpO_2 Measurement Accuracy	Adult: 70 - 100% (± 2%) Pediatric: 70 - 100% (± 3%)	Adult: 70 - 100% (± 2%) Pediatric: 70 - 100% (± 3%)
Pulse Rate Measurement Range	20 - 240 BPM	20 - 240 BPM
Pulse Rate Measurement Accuracy	± 3 BPM (no motion) ± 5 BPM (with motion)	± 3 BPM (no motion) ± 5 BPM (with motion)
SpO_2 / Pulse Rate Resolution	SpO_2: 1% Pulse Rate: 1 bpm	SpO_2: 1% Pulse Rate: 1 bpm

Table 3: Substantial Equivalence Comparison between IQvitals Zone and K110028

Characteristic	Subject Device	Predicate Device
	IQvitals Zone Wireless	**Masimo Radical 7 Pulse CO-Oximeter and Accessories (K110028)**
Pulse Oximeter Module	Masimo (SET) MX-5 OEM board	Masimo (SET) MX-5 OEM board
SpO_2 Modes	Continuous Monitoring and Off	Continuous Monitoring and Off
SpO_2 Sensor Types	Reusable and Disposable	Reusable and Disposable
SpO_2 Sensor sizes	Adult, Pediatric	Adult, Pediatric
SpO_2 Measurement Range	0-100%	0-100%
SpO_2 Measurement Accuracy	Adult: 70 - 100% (± 2%) Pediatric: 70 - 100% (± 3%)	Adult: 70 - 100% (± 2%) Pediatric: 70 - 100% (± 3%)
Pulse Rate Measurement Range	25 - 240 BPM	25 - 240 BPM
Pulse Rate Measurement Accuracy	± 3 BPM (no motion) ± 5 BPM (with motion)	± 3 BPM (no motion) ± 5 BPM (with motion)
SpO_2 / Pulse Rate Resolution	SpO_2: 1% Pulse Rate: 1 bpm	SpO_2: 1% Pulse Rate: 1 bpm

Table 4: Substantial Equivalence Comparison between IQvitals Zone and K011291

Characteristic	Subject Device	Predicate Device
	IQvitals Zone Wireless	**Exergen TemporalScanner Thermometer (K011291)**
Thermometer Module	Exergen TemporalScanner	Exergen TemporalScanner
Thermometer Type	Temporal	Temporal
Measurement Range	15.5°C to 43°C (61°F to 110°F)	15.5°C to 43°C (61°F to 110°F)
Measurement Accuracy *[within the +/- 0.6°C (+-1.0°F) range specified by ASTM E1112 standard]*	+/-0.1°C (+/- 0.2°F)	+/-0.1°C (+/- 0.2°F)
Resolution	0.1 °C / 0.1 °F	0.1 °C / 0.1 °F
Response Time	~0.04 seconds	~0.04 seconds

7. Non-clinical Bench (Performance) testing

The safety and performance of the IQvitals Zone is demonstrated through compliance with following standards:

- AAMI/ANSI ES 60601-1, Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-8, Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems
- IEC 80601-2-30, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers
- IEC 60601-2-49, Medical Electrical Equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-56, Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement

- ISO 80601-2-61, Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment

8. Clinical Testing

The clinical validation of the Midmark Non-invasive Blood Pressure (NIBP) module was conducted per ANSI / AAMI / ISO 81060-2:2013, Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type.

9. Conclusion:

Based on the intended use, design, technological characteristics and performance data provided in the submission; the proposed 'IQvitals Zone' is substantially equivalent to the referenced predicate devices, and does not raise any new concerns of safety of effectiveness.