June 12, 2026

Midmark Corporation
Jessica Hembrey
Regulatory Affairs Specialist
60 Vista Dr.
Versailles, Ohio 45380

Re: K253196
Trade/Device Name: Midmark 800 Digital Vital Signs Device (1-300-0100, 1-300-0200, 1-300-0300, 1-300-0400)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, FLL, BZQ
Dated: May 13, 2026
Received: May 14, 2026

Dear Jessica Hembrey:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
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.	K253196

Please provide the device trade name(s).

Midmark 800 Digital Vital Signs Device (1-300-0100, 1-300-0200, 1-300-0300, 1-300-0400)

Please provide your Indications for Use below.

The Midmark 800 Digital Vital Signs Device is intended for use by clinicians and other medically qualified personnel to measure specific physiologic parameters in adult and pediatric patients.

The device provides the following non-invasive measurements for patients 2 years and older, unless otherwise specified:

- Non-Invasive Blood Pressure (NIBP): for patients aged 3 years and older
- Pulse Rate
- Body Temperature (temporal artery)
- Functional Oxygen Saturation (SpO_2 - optional)
- Respiration Rate from Photoplethysmogram (RRp - optional)

The Midmark 800 Digital Vital Signs Device is intended for screening, spot-checking, or confirmation of vital signs, with data transfer to an electronic medical record (EMR) system.

It is indicated for use in ambulatory care clinics, hospitals, and other points of care, under the direction of trained medical personnel.

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

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

Midmark 800 Digital Vital Signs Device 510(k) Summary

Designing better care.™

Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380
1-800-MIDMARK
midmark.com

In accordance with 21 CFR §807.92, a 510(k) summary is provided below with the required information.

1. Administrative Information

Table 1. Administrative Information	
Date Summary Prepared	09/26/2025
510(k) Sponsor Address	Midmark Corporation 60 Vista Drive Versailles, Ohio 45380
Contact Person	Jessica Hembrey Regulatory Affairs Specialist Email: jhembrey@midmark.com Phone: 847.415.9742 Fax: 937.526.8482
Trade Name	Midmark 800 Digital Vital Signs Device (1-300-0100, 1-300-0200, 1-300-0300, 1-300-0400)
Common Name	Vital Signs Device
Classification Name	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms) (21 CFR 870.2300, Product Code MWI)
Associated Product Codes	DQA, DXN, FLL, BZQ
Device Classification	Class II
Review Panel	Cardiovascular

2. Equivalent Predicate Comparators

Table 2. Predicate Devices

Manufacturer Name	Predicate	Trade Name	510(k) No.	Decision Date
Midmark Corporation	Primary	IQvitals Zone	K161909	November 17, 2016
Masimo Corporation	Secondary	Masimo Radical-7 Pulse CO-Oximeter and Accessories	K193242	February 27, 2020

3. Indications for Use

The Midmark 800 Digital Vital Signs Device is intended for use by clinicians and other medically qualified personnel to measure specific physiologic parameters in adult and pediatric patients.

The device provides the following non-invasive measurements for patients 2 years and older, unless otherwise specified:

- Non-invasive Blood Pressure (NIBP): for patients aged 3 years and older
- Pulse Rate
- Body Temperature (temporal artery)
- Functional Oxygen Saturation (SpO_2 - optional)
- Respiration Rate from Photoplethysmogram (RRp - optional)

The Midmark 800 Digital Vital Signs Device is intended for screening, spot-checking, or confirmation of vital signs, with data transfer to an electronic medical record (EMR) system.

It is indicated for use in ambulatory care clinics, hospitals, and other points of care, under the direction of trained medical personnel.

4. Device Models

Table 3. Midmark 800 Digital Vital Signs Device Configurations

Finished Device Kit Number	Digital Vital Signs Device Model Number	Features				
		DVSD	Exergen Temporal Thermometer	Nellcor SpO_2	Masimo SpO_2	Masimo SpO_2 w/RRp
4-000-0801	1-300-0100	X	X	-	-	-
4-000-0802	1-300-0200	X	X	X	-	-
4-000-0803	1-300-0300	X	X	-	X	-
4-000-0804	1-300-0400	X	X	-	-	X

5. Device Description

The Midmark 800 Digital Vital Signs Device is a non-invasive, multi-parameter monitoring system intended for use by clinicians and medically qualified personnel to obtain and display physiological measurements in adult and pediatric patients. The device is designed for spot-checking, screening, or confirmation of vital signs, with optional data transfer to an electronic medical record (EMR) system.

The device measures non-invasive blood pressure (NIBP), pulse rate, body temperature using an Exergen temporal artery thermometer cleared under K011291, and functional oxygen saturation (SpO_2) using either a Nellcor SpO_2 module cleared under K123581 or a Masimo SpO_2 module cleared under K193242. The OEM modules and sensors are used

without modification to their technological characteristics and intended use, and have been validated for compatibility and performance with the Midmark 800 Digital Vital Signs Device. When configured with compatible components, the device also provides optional measurement of respiration rate derived from the photoplethysmogram (RRp).

The Midmark 800 is available in multiple model variants offering different combinations of measurement parameters and accessories, as shown in **Table 3**.

Device specifications and technological Characteristics are provided in **Table 4**.

6. Device Specifications and Technological Characteristics

Table 4 provides a comparison of the intended use and technological characteristics of the Midmark 800 Digital Vital Signs Device and its predicate devices. As shown, the Midmark 800 has the same intended use as the primary predicate device and incorporates similar technological characteristics as multi-parameter vital signs monitors, each measuring non-invasive blood pressure (NIBP), pulse rate, body temperature, and optional SpO_2.

The Midmark 800 Digital Vital Signs Device differs from the primary predicate in that it is designed for spot-check monitoring rather than continuous monitoring, eliminates wireless communication in favor of USB-C wired connectivity, and incorporates user interface updates to improve readability and navigation. In addition, the Midmark 800 supports an optional Respiration Rate from Photoplethysmogram (RRp) feature through integration of a compatible Masimo SpO_2 module. The Masimo Radical-7 serves as the secondary predicate for this sole purpose. Validation testing, risk analysis, and comparative evaluation confirm that these technological differences do not raise new questions of safety or effectiveness.

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics

Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
Device Name	**Midmark 800 DVSD**	**Midmark IQvitals Zone**	**Masimo Radical-7**
Manufacturer	Midmark Corporation	Midmark Corporation	Masimo
510(k) Number	*TBD*	K161909	K193242
Device Classification	Class II	Class II	Class II
Product Code(s)	**MWI, DXN, DQA, FLL, BZQ**	**MWI, DXN, DQA, FLL**	**MWI, DXN, DQA, FLL, BZQ, CCK, DPZ**
Intended Use / Indications for Use	The Midmark 800 Digital Vital Signs Device is intended for use by clinicians and other medically qualified personnel to measure specific physiologic parameters in adult and pediatric patients. The device provides the following non-invasive measurements for patients 2 years and older, unless otherwise specified:	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 arterial	The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics			
Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
	• Non-invasive Blood Pressure (NIBP): for patients aged 3 years and older • Pulse Rate • Body Temperature (temporal artery) • Functional Oxygen Saturation (SpO_2 - optional) • Respiration Rate from Photoplethysmogram (RRp - optional) The Midmark 800 Digital Vital Signs Device is intended for screening, spot-checking, or confirmation of vital signs, with data transfer to an electronic medical record (EMR) system. It is indicated for use in ambulatory care clinics, hospitals, and other points of care, under the direction of trained medical personnel.	hemoglobin (SpO_2) 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 patients in general medical locations, hospitals and alternative care environments.	or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms. The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities. The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics			
Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
			motion conditions in hospitals and hospital-type facilities. The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities. The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.
Patient Population	Adult & Pediatric (3+ years for NIBP; 2+ years for thermometer, SpO_2 and RRp)	Adult and pediatric (ages 3+)	Adult and pediatric
Accessories	SpO_2 sensors, temporal scanner, BP cuffs	SpO_2 sensors, temporal scanner, BP cuffs	SpO_2 sensors
Available Module Configurations	Non-invasive Blood Pressure (NIBP) Pulse Oximeter Pulse Oximeter with optional RRp Temperature	Noninvasive Blood Pressure (NIBP) Pulse Oximeter Temperature	Pulse Oximeter
Connectivity	USB, wired data transfer	USB, Bluetooth, wireless capability	USB, Ethernet, optional wireless
Biocompatibility	Monitor housing is non-patient-contacting. OEM accessories (SpO_2 sensors, temperature probes, BP cuffs) have FDA-cleared biocompatibility.	Monitor housing is non-patient-contacting. Accessories have FDA-cleared biocompatibility.	SpO_2 accessory has FDA-cleared biocompatibility.

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics			
Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
Non-Invasive Blood Pressure (NIBP) Module Specifications			
Operating Principle / Measurement Method	Oscillometric	Oscillometric	N/A
NIBP Range	Systolic: 50-260 mmHg Mean: 30-230 mmHg Diastolic: 20-210 mmHg	Systolic: 50-260 mmHg Mean: 30-230 mmHg Diastolic: 20-210 mmHg	N/A
NIBP Measurement Accuracy	±5 mmHg (standard deviation ≤8 mmHg)	±5 mmHg (standard deviation < 8 mmHg)	N/A
NIBP Measurement Resolution	1 mmHg	1 mmHg	N/A
Pulse Rate Range	40-200 bpm	40-200 bpm	N/A
Pulse Rate Accuracy	±5 bpm or ±5%, whichever is greater	±3 bpm or ±5%, whichever is greater	N/A
Pulse Rate Resolution	1 bpm	1 bpm	N/A
Initial Cuff Pressure	Automatic or User-selectable	Automatic or User-selectable	N/A
Maximum Cuff Pressure	280 ± 5 mmHg	280 ± 5 mmHg	N/A
Overpressure Cutoff	300 ± 30 mmHg	300 ± 30 mmHg	N/A
Cuff Types	Reusable	Reusable and single use cuffs	N/A
Cuff Sizes	Child Small Adult Adult Adult Long Large Adult Large Adult Long Thigh	Child Small Adult Adult Adult Long Large Adult Large Adult Long Thigh	N/A
Masimo Pulse Oximetry Specifications			
Pulse Oximeter	Rainbow SET Technology Board	MX Board (Rainbow SET)	Rainbow SET Technology Board
SpO_2 Modes	Spot Monitoring	Continuous Monitoring	Continuous and Spot Monitoring
SpO_2 Sensor Types	Reusable	Reusable and Disposable	Reusable
SpO_2 Sensor Sizes	Adult and Pediatric	Adult and Pediatric	Adult and Pediatric
SpO_2 Measurement Range	0 - 100%	0 - 100%	0 - 100%
SpO_2 Measurement Accuracy	No Motion: 70-100% (±2%) With Motion: 70-100% (±3%)	No Motion: 70 - 100% (± 2%) With Motion: 70 - 100% (± 3%)	No Motion: 70-100% (±2%)

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics			
Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
			With Motion: 70-100% (±3%)
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
Pulse Rate Measurement Range	25–240 bpm	25-240 bpm	25–240 bpm
Pulse Rate Measurement Accuracy	No motion: ±3 bpm With Motion: ±5 bpm	No motion: ±3 bpm With Motion: ±5 bpm	No motion: ±3 bpm With Motion: ±5 bpm
Respiration Rate Measurement Method	Respiration rate from photoplethysmogram (RRp)	N/A	Respiration rate from photoplethysmogram (RRp)
RRp Measurement	4 - 70 rpm	N/A	4 – 70 rpm
RRp Measurement Accuracy	±3 rpm ARMS, ±1 rpm mean error	N/A	±3 rpm ARMS, ±1 rpm mean error
Nellcor Pulse Oximetry Specifications			
Pulse Oximeter	Nellcor NELL-1	Nellcor NELL-1	N/A
SpO_2 Modes	Spot Monitoring	Continuous Monitoring	N/A
SpO_2 Sensor Types	Reusable	Reusable	N/A
SpO_2 Sensor Sizes	Adult and Pediatric	Adult and Pediatric	N/A
SpO_2 Measurement Range	1 - 100%	0 - 100%	N/A
SpO_2 Measurement Accuracy	No Motion: 70 - 100% (±2%) With Motion: 70 - 100% (±3%)	No Motion: 70 - 100% (± 2%) With Motion: 70 - 100% (±3%)	N/A
SpO_2 / Pulse Rate Resolution	SpO_2: 1% Pulse Rate: 1 bpm	SpO_2: 1% Pulse Rate: 1 bpm	N/A
Pulse Rate Measurement Range	20 - 250 bpm	20 - 240 bpm	N/A
Pulse Rate Measurement Accuracy	No motion: ±3 bpm With Motion: ±5 bpm	No motion: ±3 bpm With Motion: ±5 bpm	N/A
Temperature Measurement Method			
Temperature Sensor	Exergen Temporal Scanner	Exergen Temporal Scanner	N/A
Measurement Method	Infrared temporal artery measurement	Infrared temporal artery measurement	N/A
Temperature Measurement Range	15.5°C - 43°C (60°F - 110°F)	15.5°C - 43°C (60°F - 110°F)	N/A
Clinical Accuracy	±0.1°C (±0.2°F)	±0.1°C (±0.2°F)	N/A
Response Time	~0.04 seconds	~0.04 seconds	N/A

Table 4. Substantial Equivalence Table – Comparison of Technological Characteristics			
Characteristic	**Subject Device**	**Primary Predicate**	**Secondary Predicate**
Display Time	30 seconds	30 seconds	N/A
Resolution	0.1°C / 0.1°F	0.1°C / 0.1°F	N/A
Additional Specifications for the Midmark 800			
Alarms / Conditions	No patient alarms. Informational alerts (e.g., measurement error, peripheral connection) provided via user interface.	High priority: NIBP systolic, MAP, diastolic high or low; SpO_2 high or low, and some high priority technical alarms Medium priority: SpO_2 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.	N/A
Product Weight	3.9 lb	3.9 lb	N/A
Dimensions	9.3" x 6.9" x 2.9" (LxWxH)	10.5" x 4" x 7" (LxWxH)	N/A
Power Supply	100-240VAC, 50/60Hz OR Rechargeable lithium-ion battery (7.4V)	100-240VAC, 50-60 Hz OR Lithium-ion battery (7.2V)	N/A
Environmental Operating Conditions	Temperature: 10°C to 40°C Humidity: 15%-90% RH (non-condensing) Altitude: Up to 10,000 feet	Temperature: 10°C to 40°C Humidity: 15%-90% RH (non-condensing) Altitude: Up to 10,000 feet	N/A
Comparison of Compliance with FDA-Recognized Standards			
Compliance with FDA-Recognized Consensus Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 80601-2-30 IEC 80601-2-49 ISO 81060-2 ISO 80601-2-56 ISO 80601-2-61 IEC 62133-2 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 80601-2-30 IEC 80601-2-49 ISO 81060-2 ISO 80601-2-56 ISO 80601-2-61	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 ISO 80601-2-61 IEC 62304

7. Non-Clinical Performance Data

Non-clinical testing and evaluations were performed for the Midmark 800 Digital Vital Signs Device. A summary of evaluations is shown in **Table 5**. Based on the results of studies performed, the Midmark 800 Digital Vital Signs Device does not raise new issues of safety or effectiveness.

Table 5. Non-Clinical Performance Data

Standard	Standard Name
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. Amd2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
IEC 60601-1-2 Edition 4.1:2020-09	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2 2020-07	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
IEC 62366-1 Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 80601-2-49 Edition 1.0 2018	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
ISO 80601-2-56 Edition 2.1 2021-02	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 Edition 2.0 2017-12	Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
ISO 10993-1 Edition 5.0 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62133-2 Edition 1.1 2021-07	Safety requirements for portable sealed secondary lithium batteries – Part 2: Lithium systems

8. Clinical Performance Data

Clinical validation of the Midmark Non-Invasive Blood Pressure (NIBP) Module was conducted under ISO 81060-2:2018/Amd 2:2024 in a non-randomized, dual-observer, single-center study. Adult and pediatric subjects participated across multiple studies evaluating the Linear and Step algorithms. The device met all accuracy criteria for systolic and diastolic blood pressure in both adult and pediatric populations. Following the validation procedure outlined in *ISO 81060-2:2018/AMD 1:2020/AMD 2:2024 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type*, the Midmark NIBP Module with the Step and Linear algorithms passed the criteria systolic and diastolic requirements for all study subsets.

A second single-center clinical study was conducted to evaluate pulse rate derived from the Midmark 800 NIBP module. Pulse rate accuracy was assessed using a single-lead ECG reference device with simultaneous acquisition in adult and pediatric participants. The results demonstrated equivalent pulse rate performance of the subject device relative to

the ECG reference device for the evaluated cuff sizes and measurement methods. Both the Step and Linear measurement methods were evaluated for pulse rate. For the Linear method, data from a single cuff size were not included in the analysis.

A summary of evaluations is shown in **Table 6**.

Table 6. Clinical Performance Data

Standard	Standard Name
IEC 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2:2018/Amd2:2024	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
ISO TS 81060-5 First Edition 2020-02	Non-invasive sphygmomanometers – Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers
ISO 14155:2020-07	Clinical investigation of medical devices for human subjects – Good clinical practice

9. Conclusion

The results from non-clinical and clinical testing demonstrate that the Midmark 800 Digital Vital Signs Device is substantially equivalent, is as safe and effective, and performs as well as the legally marketed predicate devices, the Midmark IQvitals Zone (K161909) and the Masimo Radical-7 (K193242).