April 4, 2024

Midmark Corporation
Adam Clutter
Quality Systems and Regulatory Affairs Manager
60 Vista Drive
Versailles, Ohio 45380

Re: K233026
Trade/Device Name: Midmark Smart M9® Sterilizer,
Midmark Smart M11® Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: March 7, 2024
Received: March 8, 2024

Dear Adam Clutter:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical

and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233026

Device Name
Midmark Smart M9® Sterilizer
Midmark Smart M11® Sterilizer

Indications for Use *(Describe)*

The Midmark Smart M9® and Smart M11® Sterilizers can be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization. Refer to Standard Cycle Parameters for detailed information.

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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Standard Cycle Parameters

Cycle Type	Cycle Parameters			Drying Time [2]	Items to be Sterilized *(Always follow the item manufacturer's recommendations for sterilization.)*	M9 Maximum Capacity [4]	M11 Maximum Capacity [4]
	Temperature Minimum	Time	Pressure [1] Reference				
1 Wrapped	132°C (270°F)	4 min.	186 kPa (27.1 psi)	30 min.	• Pouched or wrapped items manufacturers recommend for exposure at 132°C (270°F) for 4 minutes. • Wrapped cassettes. • Dental Handpieces (wrapped or unwrapped)	3,629 grams (8.0 lb) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb) total	4,082 grams (9.0 lb) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb) total
2 Wrapped	135°C (275°F)	3 min.	214 kPa (31 psi)	30 min.	• Pouched or wrapped items manufacturers recommend for exposure at 135°C (275°F) for 3 minutes. • Wrapped cassettes. • Dental Handpieces (wrapped or unwrapped)	3,629 grams (8.0 lb) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb) total	4,082 grams (9.0 lb) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb) total
Delicate	121°C (250°F)	30 min.	104 kPa (15 psi)	30 min.	• Textiles and surgical packs wrapped for sterilization.[3] • Items, except liquids, manufacturers recommend for exposure at 121°C (250°F) for 30 minutes.	3,629 grams (8.0 lb) or 590 grams (1.3 lb) textile load	4,082 grams (9.0 lb) or 2 packs each @ 590 grams (1.3 lb) textile load
Unwrapped	132°C (270°F)	3 min.	186 kPa (27.1 psi)	30 min.	• Instruments loose on a tray. • Open glass or metal canisters. • Tubing not used in surgical procedures. (Max. length - 40 in and Min. inside diameter - .187 in) • Loose items manufacturers recommend for exposure at 132°C (270°F) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*	3,629 grams (8.0 lb)	4,082 grams (9.0 lb)

1. *The pressures shown in this table are at sea level and are for reference only. These are the ideal pressure of saturated steam at the sterilization temperature. The pressures on the sterilizer display may be higher.*
2. *Dry time can be changed from 5 to 60 minutes. (IUSS dry time can be changed from 1 to 5 minutes.) Refer to* ***Standard Cycle Operation****.*
3. *Allow a minimum of 6.4 mm (1/4 in) space between each pack and from the chamber wall.*
4. *The default dry time may need increased due to variations in load configuration, wrapping materials and the environment to completely dry the chamber contents at these capacities.*

Midmark® Smart Sterilizers 510(k) Summary
K233026

Designing better care.™

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

As required by the Safe Medical Devices Act (SMDA) of 1990 and 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	March 28, 2024
510(k) Sponsor Address	Midmark Corporation 60 Vista Drive Versailles, Ohio 45380
Contact Person	Adam Clutter Quality Systems and Regulatory Affairs Manager Email: aclutter@midmark.com Phone: 937-526-8474 Fax: 937-526-8482
Trade Name	Midmark Smart M9® Sterilizer, Midmark Smart M11® Sterilizer
Common Name	Table Top Steam Sterilizer
Classification Name	21 CFR §880.6880 Steam sterilizer (Product Code FLE)
Device Classification	Class II
Review Panel	General Hospital

2. Equivalent Predicate Comparators

Table 2. Predicate Device

Manufacturer Name	Trade Name	510(k) No.	Decision Date

Table 2. Predicate Device

Midmark Corporation	Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and Ritter M9D AutoClave® Automatic Sterilizers	K163337	August 31, 2017

3. Indications for Use

The Midmark Smart M9® and Smart M11® Sterilizers can be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization. Refer to Standard Cycle Parameters for detailed information.

Standard Cycle Parameters

Cycle Type	Cycle Parameters			Drying Time [2]	Items to be Sterilized *(Always follow the item manufacturer's recommendations for sterilization.)*	M9 Maximum Capacity [4]	M11 Maximum Capacity [4]
	Temperature Minimum	Time	Pressure [1] Reference				
Wrapped	132°C (270°F)	4 min.	186 kPa (27.1 psi)	30 min.	• Pouched or wrapped items manufacturers recommend for exposure at 132°C (270°F) for 4 minutes. • Wrapped cassettes. • Dental Handpieces (wrapped or unwrapped)	3,629 grams (8.0 lb) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb) total	4,082 grams (9.0 lb) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb) total
Wrapped	135°C (275°F)	3 min.	214 kPa (31 psi)	30 min.	• Pouched or wrapped items manufacturers recommend for exposure at 135°C (275°F) for 3 minutes. • Wrapped cassettes. • Dental Handpieces (wrapped or unwrapped)	3,629 grams (8.0 lb) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb) total	4,082 grams (9.0 lb) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb) total
Delicate	121°C (250°F)	30 min.	104 kPa (15 psi)	30 min.	• Textiles and surgical packs wrapped for sterilization.[3] • Items, except liquids, manufacturers recommend for exposure at 121°C (250°F) for 30 minutes.	3,629 grams (8.0 lb) or 590 grams (1.3 lb) textile load	4,082 grams (9.0 lb) or 2 packs each @ 590 grams (1.3 lb) textile load
Unwrapped	132°C (270°F)	3 min.	186 kPa (27.1 psi)	30 min.	• Instruments loose on a tray. • Open glass or metal canisters. • Tubing not used in surgical procedures. (Max. length - 40 in and Min. inside diameter - .187 in) • Loose items manufacturers recommend for exposure at 132°C (270°F) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*	3,629 grams (8.0 lb)	4,082 grams (9.0 lb)

1. *The pressures shown in this table are at sea level and are for reference only. These are the ideal pressure of saturated steam at the sterilization temperature. The pressures on the sterilizer display may be higher.*
2. *Dry time can be changed from 5 to 60 minutes. (IUSS dry time can be changed from 1 to 5 minutes.) Refer to* ***Standard Cycle Operation****.*
3. *Allow a minimum of 6.4 mm (1/4 in) space between each pack and from the chamber wall.*
4. *The default dry time may need increased due to variations in load configuration, wrapping materials and the environment to completely dry the chamber contents at these capacities.*

4. Models

Table 3. Models

Model Name	Model Number	Input Voltage
Midmark Smart M9® Sterilizer	M9-050	115V
	M9-052	115V
Midmark Smart M11® Sterilizer	M11-050	115V

Table 3. Models		
Model Name	**Model Number**	**Input Voltage**
	M11-051	230V
	M11-052	115V

5. Device Description

The Midmark Smart M9® and Smart M11® Sterilizers utilize steam flush pressure pulse (SFPP) technology to achieve sterilization on heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization.

The Midmark Smart M9® and Smart M11® Sterilizers are compact, self-contained portable units. They can be placed on any level support surface where an electrical outlet is available with no other installation required. The M9 sterilizer models are the smaller of the models with a 9 in (22.9 cm) diameter x 15 in (38.1 cm) deep stainless-steel chamber. The M11 sterilizer models have an 11" (27.9 cm) diameter x 18" (45.7 cm) deep stainless-steel chamber.

The Midmark Smart M9® and Smart M11® Sterilizers use saturated steam at high pressure and temperature as the sterilizing agent to kill infectious bio-organisms on items placed in the chamber for processing. They use the dynamic Steam Flush Pressure Pulse (SFPP) cycle type for the pre-set cycles that include a 4-minute 270°F and a 3-minute 275°F cycle for wrapped or pouched instruments (including dental handpieces) and cassettes, a 30-minute 250°F cycle for textiles and instrument packs requiring a lower temperature, and a 3-minute 270°F cycle for unwrapped instruments. The 3-minute 275°F is added to align with Table B.2 in AAMI TIR12:2020. In the SFPP type cycle, residual air is removed from the chamber and its contents by a series of controlled pressure pulses and steam flushes.

The Midmark Smart M9® and Smart M11® Sterilizers are designed to automate the sterilization process, to the extent possible, and the user interface on the subject models extends this capability to include sterilization record keeping. To use the sterilizer, the operator fills the water reservoir with water (distilled or purified) and loads the included trays with properly cleaned and prepped instruments for sterilization. The loaded trays are then placed inside the chamber, and the chamber door is manually closed by the operator. Based on the cycle parameters that are appropriate for the type of load being processed, the operator then selects the appropriate sterilization cycle on the user interface. On the subject units there are options for the user to enter load type and indicator information. Once the cycle is selected and the operator presses "Start," there is an option to capture the identification of the operator. The sterilizer then automatically performs all the operations necessary to complete the sterilization process without further interaction from the operator. The sterilization cycle is composed of several phases which include Filling, Heating, Sterilization, Venting, and Drying. Audible signals indicate cycle initiation, completion, and/or interruption, and the user interface provides visual communication of device status, operator instructions, and troubleshooting information. The LED light bar also provides an estimate of the cycle progression. At the conclusion of the cycle there is another option to capture the identification of the operator that unloads and approves or rejects the results of the sterilization cycle.

All sterilizer cycle and user maintenance (Routine Care) records are stored internally on an SD card. Midmark has developed a Digital Ecosystem Connectivity Module that is incorporated into the Midmark Smart M9® and Smart M11® Sterilizers which adds the ability to transfer electronic sterilization records to the Midmark cloud and to remotely view the current status of, or cycle history for multiple sterilizers. Optional features and settings that may be distributed to multiple sterilizers from the cloud include distribution of software updates to the connectivity module, compliance settings, and entering the results of biological indicator tests. Connectivity is not needed to perform the sterilizer's intended use, and connecting a sterilizer does not change the intended use. Device specifications are provided in Table 4.

Table 4. Specifications

Specification	Smart M9® Sterilizer	Smart M11® Sterilizer
Physical dimensions:		
Overall Length with Plug	20.5 in (52.0 cm)	23.5 in (59.7 cm)
Overall Width	15.8 in (40.1 cm)	17.8 in (45.2 cm)
Overall Height	16.6 in (42.2 cm)	18.6 in (47.2 cm)
Required Support Surface	19.8 in x 23.5 in (50.3 cm x 59.7 cm)	21.8 in x 26.5 in (55.4 cm x 67.3 cm)
Chamber Size	9 in diameter x 15 in deep (22.9 cm x 38.1 cm)	11 in diameter x 18 in deep (27.9 cm x 45.7 cm)
Trays, Large	7-5/16 in x 12 in x 7/8 in (18.6 cm x 30.5 cm x 2.2 cm)	9-1/8 in x 15-1/4 in x 7/8 in (23 cm x 38.7 cm x 2.2 cm)
Trays, Small	5-5/8 in x 12 in x 7/8 in (14.3 cm x 30.5 cm x 2.2 cm)	6-3/4 in x 15-1/4 in x 7/8 in (17 cm x 38.7 cm x 2.2 cm)
Weights:		
Weight with Empty Reservoir	82 lb. (37.2 kg)	99 lb. (44.9 kg)
Weight with Shipping Carton	92 lb. (41.7 kg)	131 lb. (59.4 kg)
Water Reservoir Capacity	1.1 gallons (4.1 liters) full, 0.6 gallons (2.3 liters) usable	1.4 gallons (5.3 liters) full, 0.8 gallons (3.0 liters) usable
Electrical Ratings:		
Note: A separate (dedicated) circuit is required for these sterilizers. Sterilizer should not be connected into an electrical circuit with other appliances or equipment unless circuit is rated for the additional load.		
115 Volt Models	115 VAC, 12 Amp, 50/60 Hz	115 VAC, 12 Amp, 50/60 Hz
230 Volt Models	Not Applicable	230 VAC, 6.4 Amp, 50/60 Hz
Fuse Ratings:		

Table 4. Specifications

Specification		Smart M9® Sterilizer	Smart M11® Sterilizer
115 VAC	F1	15 Amp, 250 V, Fast Acting, 0.250 in Dia. x 1.250 in L (6.35 mm x 31.75 mm)	15 Amp, 250 V, Fast Acting, 0.250 in Dia. x 1.250 in L (6.35 mm x 31.75 mm)
	F2	15 Amp, 250 V, Fast Acting, 0.250 in Dia. x 1.250 in L (6.35 mm x 31.75 mm)	15 Amp, 250 V, Fast Acting, 0.250 in Dia. x 1.250 in L (6.35 mm x 31.75 mm)
	F3	2.5 Amp, 250 V, Time Delay/Slow-Blow, 5.20 mm Dia. x 20.00 mm L (0.205 in x 0.787 in)	2.5 Amp, 250 V, Time Delay/Slow-Blow, 5.20 mm Dia. x 20.00 mm L (0.205 in x 0.787 in)
230 VAC	F1	Not Applicable	8 Amp, 250 V, Fast Acting, 5.20 mm Dia. x 20.00 mm L (0.205 in x 0.787 in)
	F2	Not Applicable	8 Amp, 250 V, Fast Acting, 5.20 mm Dia. x 20.00 mm L (0.205 in x 0.787 in)
	F3	Not Applicable	2.5 Amp, 250 V, Time Delay/Slow-Blow, 0.250 in Dia. x 1.250 in L (6.35 mm x 31.75 mm)
Safety Valve Setting		43 psi (296 kPa)	43 psi (296 kPa)
Heat Emission		5000 BTU / hr. during operation	5000 BTU / hr. during operation
Operating Environment:			
Ambient Temperature Range		68°F to 104°F (+20°C to +40°C)	68°F to 104°F (+20°C to +40°C)
Relative Humidity		< 80% (non-condensing)	< 80% (non-condensing)
Operating Altitude		< 9842 ft (3000 m) above sea level	< 9842 ft (3000 m) above sea level

6. Technological Characteristics

Refer to Table 5 for a comparison of Midmark Smart M9® and Smart M11® Sterilizer technological characteristics with those of its predicate. Changes made to the Midmark Smart M9® and Smart M11® Sterilizers do not raise new issues of safety or effectiveness in terms of Indications for Use, design, material, chemical composition, principle of operation, energy source, and performance.

Table 5. Predicate Comparison

Characteristic	Subject Device: Midmark Smart M9® and Smart M11® Sterilizers	Predicate Device: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers	Comparison
510(k) Clearance	K233026	K163337	Not Applicable
Regulation Number	21 CFR §880.6880 Steam sterilizer	21 CFR §880.6880 Steam sterilizer	Same
Product Code	FLE	FLE	Same
Intended Use	The Midmark Smart M9® and Smart M11® Sterilizers can be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization. Refer to Standard Cycle Parameters for detailed information.	The Midmark and Ritter M9, M9D and M11 Steam Sterilizers can be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization. Refer to Guidelines for loading and Standard Cycle Parameters for detailed information.	Same
Standard Cycle Parameters	Wrapped 1 Cycle 4 min./ 132°C (270°F) / 30 min.	Pouches Cycle 4 min./ 132°C (270°F) / 30 min. Handpiece Cycle 4 min./ 132°C (270°F) / 30 min.	Same
	Wrapped 2 Cycle 3 min./ 135°C (275°F) / 30 min.	Not Available	Different
	Delicate Cycle 30 min./ 121°C (250°F) / 30 min.	Packs Cycle 30 min./ 121°C (250°F) / 30 min.	Same
	Unwrapped Cycle 3 min./ 132°C (270°F) / 30 min.	Unwrapped Cycle 3 min./ 132°C (270°F) / 30 min.	Same
Dry Time	5 to 60 minutes. (Immediate Use Steam Sterilization dry time can be changed from 1 to 5 minutes.)	0 to 60 minutes.	Same
M9 Maximum Capacity			

Table 5. Predicate Comparison

Characteristic	Subject Device: Midmark Smart M9® and Smart M11® Sterilizers	Predicate Device: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers	Comparison
Wrapped 1 Cycle	3,629 grams (8.0 lb.) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb.) total	8 handpieces with other instruments 3629 grams (8.0 lb.)	Same
Wrapped 2 Cycle	3,629 grams (8.0 lb.) or 8 handpieces (2 per tray) with other instruments 3,629 grams (8.0 lb.) total	Not available	Different
Delicate Cycle	3,629 grams (8.0 lb.) or 590 grams (1.3 lb.) textile load	4752 cm^3 (290 in^3)	Similar
Unwrapped Cycle	3,629 grams (8.0 lb.)	3,629 grams (8.0 lb.)	Same
M11 Maximum Capacity			
Wrapped 1 Cycle	4,082 grams (9.0 lb.) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb.) total	8 handpieces with other instruments 4,082 grams (9.0 lb.)	Same
Wrapped 2 Cycle	4,082 grams (9.0 lb.) or 8 handpieces (2 per tray) with other instruments 4,082 grams (9.0 lb.) total	Not Available	Different
Delicate Cycle	4,082 grams (9.0 lb.) or 2 packs each @ 590 grams (1.3 lb.) textile load	505 in3 (8275 cm3)	Similar

Table 5. Predicate Comparison

Characteristic	Subject Device: Midmark Smart M9® and Smart M11® Sterilizers	Predicate Device: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers	Comparison
Unwrapped Cycle	4,082 grams (9.0 lb.)	4,082 grams (9.0 lb.)	Same
Controls, Features, and Data Records			
Sterilizer Control	Microcontroller based embedded control	Microcontroller based embedded control	Same
User Interface	LCD Touch Screen, 5-inch, 800 x 480 color display Glass cover	Membrane switch with LCD display (2 row x 20 character) Polyester overlay	Different
Operator Alerts	Audible signals	Audible signals	Same
	Visual signals via touch screen display and a full-width LED light bar	Visual signals via LCD display	Different
Data Records	Built-in communication module with wireless and ethernet available network connections; optional USB thumb drive accessory	Optional add-on Data Logger with USB thumb drive; optional thermal printer	Different
Water Fill System	Gravity fill with Chamber Water Level Sensor	Gravity fill with Chamber Water Level Sensor	Same
	Optional autofill solenoid kit	Not available	Different
Reservoir Water Level Detection	Visual Indicator	Visual indicator	Same
	PCBA Mounted Pressure Transducer	Not included	Different
Chamber Pressure Sensor	PCBA Mounted Gauge Pressure Transducer	PCBA Mounted Gauge Pressure Transducer	Same
Overpressure Protection	ASME pressure relief valve (43 psi)	ASME pressure relief valve (40 psi)	Same
Overheat Protection	Dual Auto-Reset Thermostats 450°F (232°C)	Dual Auto-Reset Thermostats 450°F (232°C)	Same
Door Interlock	Safety rated switch	Safety rated switch	Same
	Pneumatic interlock	Not included	Different
Chamber Temperature Sensor	Platinum RTD	Platinum RTD	Same

Table 5. Predicate Comparison

Characteristic	Subject Device: Midmark Smart M9® and Smart M11® Sterilizers	Predicate Device: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers	Comparison
Cooling System	Three DC fans	Single AC fan	Different
Other Sensors	PCBA circuitry to monitor voltage/current, altimeter with microcontroller embedded control	Not Included	Different
Dry Cycle	Door Automatically Opens Partially (Motor Driven) while heater cycled on/off	Door Automatically Opens Partially (Motor Driven) while heater cycled on/off	Same
Design and Materials			
Chamber	Stainless Steel M9 – 9 in. dia. X 15 in. deep M11 - 11 in. dia. x 18 in. deep	Stainless Steel M9 – 9 in. dia. X 15 in. deep M11 - 11 in. dia. x 18 in. deep	Same
Chamber Door	Double Hinge Painted carbon steel with stainless steel liner	Double Hinge Painted carbon steel with stainless steel liner	Same
Door Latch	Double bolt latch with Automatic opening and closing Zinc alloy, stainless steel, and heat-treated carbon steel	Double bolt latch with Automatic opening and Manual closing Stainless steel and heat-treated carbon steel	Different
Door Gaskets	High Temperature Silicon Rubber	High Temperature Silicon Rubber	Same
Door Motor	Low voltage DC powered gearmotor heat-treated steel geartrain die-cast metal housing	High voltage AC powered gearmotor heat-treated steel geartrain die-cast metal housing	Different
Standard Tray Rack	Formed wire stainless steel	Formed sheet metal stainless steel	Similar
Trays	2 small and 2 large wire mesh stainless steel trays	2 small and 2 large formed perforated stainless-steel trays	Similar
Water Reservoir	Copolyester plastic M9 - 1.1 gal. M11 - 1.4 gal.	Polyethylene Plastic M9 - 1.1 gal. M11 - 1.4 gal.	Similar

Table 5. Predicate Comparison

Characteristic	Subject Device: Midmark Smart M9® and Smart M11® Sterilizers	Predicate Device: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers	Comparison
Water Fill Valve	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Same
Heater	Immersion Heater (1360 W nominal, 115V and 230V models) Incoloy 800 sheath with stainless steel bulkhead fittings	Immersion Heater (1425 W maximum, 115V models) (1500 W maximum, 230V models) Incoloy 800 sheath with stainless steel bulkhead fittings	Same
Air Removal Valve	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Same
Vent Valve	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Electronic Solenoid Brass body, stainless steel piston, Viton seals	Same
Enclosure	Painted carbon steel side and back panels, stainless steel base, copolyester plastic top and door cover	Painted carbon steel side and back panels, stainless steel base, polycarbonate plastic top and door cover	Similar

7. Non-clinical Performance Data

Non-clinical evaluations were performed for the Midmark Smart M9® and Smart M11® Sterilizer. A summary of evaluations and results are shown in the table below. Based on these results of studies performed, the Midmark Smart M9® and Smart M11® Sterilizers do not raise new issues of safety or effectiveness.

Table 6. Non-Clinical Performance Data

Evaluation	Standards Used	Results
Performance	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers FDA Recognition Number 14-518	Passed; the results of the evaluation demonstrate compliance of the device to the standards.

Table 6. Non-Clinical Performance Data

Evaluation	Standards Used	Results
Safety	ANSI/UL 61010-1 Third Edition 5/12/2012 / Revised 7/19/2019 , Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements FDA Recognition Number 19-41	Passed; the results of the evaluation demonstrate compliance of the device to the standards.
	IEC 61010-2-040:2020 Edition 3.0 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials	
EMC	IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests FDA Recognition Number 19-36	Passed; the results of the evaluation demonstrate compliance of the device to the standards.
Pressure Vessel	American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section VIII, Division 1: 2023 Edition	Passed; the results of the evaluation demonstrate compliance of the device to the standards.

8. Clinical Performance Data

Clinical data was not required.

9. Conclusion

The results from the nonclinical testing demonstrate that the subject device in submission K233026, the Midmark Smart M9® and Smart M11® Sterilizers are as safe, effective, and perform as well or better than the legally marketed predicate devices Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers (K163337).