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

August 31, 2017

Midmark Corporation
Adam Clutter
Regulatory Affairs Specialist
60 Vista Dr.
Versailles, Ohio 45380

Re: K163337
Trade/Device Name: Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and Ritter M9D AutoClave® Automatic Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: August 3, 2017
Received: August 3, 2017

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 (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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163337

Device Name

MIDMARK and Ritter M9 and M11 UltraClave and Ritter M9D AutoClave Self-Contained Steam Sterilizer

Indications for Use *(Describe)*
The Midmark and Ritter M9 and M11 UltraClave Automatic Sterilizers and the Ritter M9D AutoClave Automatic Sterilizer 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 on the following page 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	Items to be Sterilized *(Always consult the item manufacturer's recommendations for sterilization.)*
	Temp. (Min.)	Time	Press.[1] (Ref.)		
 Unwrapped	270°F (132°C)	3 min.	27.1 psi (186 kPa)	30 min.	• Instruments loose on a tray. • Open glass or metal canisters. • Tubing not used in surgical procedures. *(Max. length - 40" & Min. inside diameter - .187")* • Loose items manufacturers recommend for exposure at 270°F (132°C) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*
 Pouches	270°F (132°C)	4 min.	27.1 psi (186 kPa)	30 min.	• Pouched or loosely wrapped instruments. • Multiple layers of instruments separated by fabric. • Wrapped trays of loose instruments. • Wrapped cassettes. • Wrapped items manufactures recommend for exposure at 270°F (132°C) for 4 minutes.
 Packs	250°F (121°C)	30 min.	15 psi (104 kPa)	30 min.	• Textiles and surgical packs wrapped for sterilization. • Items, except liquids, manufacturers recommend for exposure at 250°F (121°C) for 30 minutes.
 Handpieces	270°F (132°C)	4 min.	27.1 psi (186 kPa)	30 min.	• Dental handpieces (wrapped or unwrapped). *Note: Verify acceptability of sterilization parameters with handpiece manufacturer.*

1. *The pressure shown in this table is for reference only. It's the ideal pressure of saturated steam at the sterilization temperature. The pressure shown on the sterilizer display may be higher.*

Description of Validated Loads

M9 Maximum Capacities			
Load Type	***Large Tray***	***Small Tray***	***Total***
Solid Instruments	2.4 lbs. (1089 grams) or	1.6 lbs. (726 grams) or	8.0 lbs. (3629 grams) or
Handpieces	2 handpieces with other instruments 2.4 lbs. (1089 grams) or	2 handpieces with other instruments 1.6 lbs. (726 grams) or	8 handpieces with other instruments 8.0 lbs. (3629 grams) or
Packs*	90 in3 ≤ 1.25 in. thick (1475 cm3 ≤ 3.2 cm thick)	55 in3 ≤ .75 in. thick (901 cm3 ≤ 1.9 cm thick)	290 in3 (4752 cm3)

M11 Maximum Capacities			
Load Type	***Large Tray***	***Small Tray***	***Total***
Solid Instruments	2.7 lbs., (1225 grams) or	1.8 lbs., (816 grams) or	9.0 lbs., (4082 grams) or
Handpieces	2 handpieces with other instruments 2.7 lbs. (1225 grams) or	2 handpieces with other instruments 1.8 lbs. (816 grams) or	8 handpieces with other instruments 9.0 lbs. (4082 grams) or
Packs*	145 in3 ≤ 1.5 in. thick (2376 cm3 ≤ 3.8 cm thick)	108 in3 ≤ 1.5 in. thick (1770 cm3 ≤ 3.8 cm thick)	505 in3 (8275 cm3)
**Allow a minimum of 1/4" (6.4 mm) space between each pack, and also from the chamber wall..*			

Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380-0286
1-800-MIDMARK
midmark.com

510(k) Summary

Table 7-1
Administrative Information

Date Summary Prepared	August 28, 2017
510(k) Sponsor Address	MIDMARK® Corporation 60 Vista Drive Versailles, Ohio 45380
Contact Person	Adam Clutter Regulatory Affairs Specialist Phone: (937) 526-8474 FAX: (937) 526-7412
Trade Name	MIDMARK® and Ritter® M9 and M11 UltraClave® and Ritter® M9D AutoClave® Self-Contained Steam Sterilizer
Common Name	Table Top Steam Sterilizer
Classification Name	Sterilizer, Steam (21 CFR §880.6880 Product Code 80 FLE)
Device Classification	Class II
Review Panel	General Hospital
510(k) Number	K163337

Table 7-2
Device Models

Model	Brand	Input Voltage	GTIN Number	Chamber Size	Door Operation
M9-04X UltraClave	Midmark	115 Vac	00841709100222	9” (22.9 cm) Dia. x 15” (38.1 cm) Deep	Automatic
	Midmark	230 Vac	00841709100239	9” (22.9 cm) Dia. x 15” (38.1 cm) Deep	Automatic
	Ritter	115 Vac	00841709100246	9” (22.9 cm) Dia. x 15” (38.1 cm) Deep	Automatic
M9D-042 Autoclave	Ritter	115 Vac	00841709100253	9” (22.9 cm) Dia. x 15” (38.1 cm) Deep	Manual
M11-04X UltraClave	Midmark	115 Vac	00841709100277	11” (27.9 cm) Dia. x 18” (45.7 cm) Deep	Automatic
	Midmark	230 Vac	00841709100284	11” (27.9 cm) Dia. x 18” (45.7 cm) Deep	Automatic
	Ritter	115 Vac	00841709100291	11” (27.9 cm) Dia. x 18” (45.7 cm) Deep	Automatic

Table 7-3
Predicate Devices

Manufacturer Name	Trade Name	510(k) Number	Decision Date	Model Number
MIDMARK® Corporation	MIDMARK® UltraClave® Steam Sterilizer	K023348	03/03/2003	M9/ M9D-02X
MIDMARK® Corporation	MIDMARK® UltraClave® Steam Sterilizer	K990189	04/19/1999	M11-00X

Device Description

The Midmark and Ritter M9 and M11 UltraClave and Ritter M9D AutoClave Self-Contained steam sterilizers are designed to sterilize medical, surgical, laboratory, and dental items, using pressurized steam. The M9 UltraClave models include a variation designated as the M9D Autoclave, the only difference being that the M9 UltraClave includes a motor to automatically open the door for drying and the M9D Autoclave is a manual model which requires the operator to open the door for drying. They are self-contained devices that are electrically powered with automatic controls for controlling time and temperature that are designed for safe, easy operation with minimal operator training.

The Midmark and Ritter M9 and M11 UltraClave and RitterM9D AutoClave Self-Contained steam sterilizers have an overall chamber dimension / volume size of 9” (22.9 cm) x 15” (38.1 cm) / 0.47 ft^3 (13.4 L) for the M9 and 11” (27.9 cm) x 18” (45.7cm) / 0.87 ft^3 (24.6 L) for the M11.

The steam sterilizers operating temperatures of the preset cycles are 250°F +6°F/-0°F (121°C +3°C/-0°C) and 270°F +6°F/-0°F (132°C +3°C/-0) which utilize a steam-flush pressure-pulse (SFPP) cycle consisting of three (3) or four (4) sequential steam flushes and pressure pulses to remove air from the sterilizing chamber and processed materials. SFPP cycles rely on diffusion of residual air in the steam and subsequent flushing of the air-steam mixture from the sterilizer resulting in shorter cycle times than gravity displacement sterilizers. Air removal is achieved with the sterilizing chamber pressure at above atmospheric pressure.

The operation of the sterilizer is controlled by a software controlled microcontroller internal to the unit. The software provides for user control of the device via a keypad on the unit’s front panel. The same software is used for the Midmark and Ritter M9 and M11 UltraClave® and Ritter M9D AutoClave® Self-Contained Steam Sterilizers.

Figure 7-1 Front Panel

Table 7-4 Cycle Parameters for M9/M11 UltraClave and M9D AutoClave

Cycle Cycle	Pre-Treatment (SFPP)	Sterilizing Temperature	Sterilizing Time	Pressure (Ref[1])	Drying Time
Unwrapped Cycle	3 Pulses	270°F (132°C)	3 min	27.1 psi (186 kPa)	30 min
Pouches Cycle	3 Pulses	270°F (132°C)	4 min	27.1 psi (186 kPa)	30 min
Packs Cycle	3 Pulses	250°F (121°C)	30 min	15 psi (104 kPa)	30 min
Handpiece Cycle	4 Pulses	270°F (132°C)	4 min	27.1 psi 186 kPa	30 min

Table 7-5 Description of Validated Loads

M9 Maximum Capacities			
Load Type	***Large Tray***	***Small Tray***	***Total***
Solid Instruments	2.4 lbs. (1089 grams) or	1.6 lbs. (726 grams) or	8.0 lbs. (3629 grams) or
Handpieces	2 handpieces with other instruments 2.4 lbs. (1089 grams) or	2 handpieces with other instruments 1.6 lbs. (726 grams) or	8 handpieces with other instruments 8.0 lbs. (3629 grams) or
Packs*	90 in3 ≤ 1.25 in. thick (1475 cm3 ≤ 3.2 cm thick)	55 in3 ≤ .75 in. thick (901 cm3 ≤ 1.9 cm thick)	290 in3 (4752 cm3)

M11 Maximum Capacities			
Load Type	***Large Tray***	***Small Tray***	***Total***
Solid Instruments	2.7 lbs., (1225 grams) or	1.8 lbs., (816 grams) or	9.0 lbs., (4082 grams) or
Handpieces	2 handpieces with other instruments 2.7 lbs. (1225 grams) or	2 handpieces with other instruments 1.8 lbs. (816 grams) or	8 handpieces with other instruments 9.0 lbs. (4082 grams) or
Packs*	145 in3 ≤ 1.5 in. thick (2376 cm3 ≤ 3.8 cm thick)	108 in3 ≤ 1.5 in. thick (1770 cm3 ≤ 3.8 cm thick)	505 in3 (8275 cm3)
**Allow a minimum of 1/4" (6.4 mm) space between each pack, and also from the chamber wall..*			

[1] The pressure shown in this table is for reference only. It's the ideal pressure of saturated steam at the sterilization temperature.

Table 7-6
Cycle Sequence and Display M9/M11 UltraClave and M9D AutoClave

Stage of Cycle	Description	Display
Filling	Chamber begins filling with water.	FILLING CHAMBER
	When water reaches the proper level...	CHAMBER IS FULL
Heating	Display changes as temperature and pressure in chamber changes. *(Metric units may be displayed if desired).*	HEATING – UNWRAPPED XXX°F XX.X PSI
Sterilizing	Sterilizing begins when correct temperature / pressure is reached. Time remaining in cycle counts down while current temperature / pressure in chamber is continuously updated.	STERILIZING MM:SS XXX°F XX.X PSI
Ready to Vent	*'READY TO VENT'* is displayed when 10 seconds remain in sterilization cycle.	READY TO VENT XXX°F XX.X PSI
Fast Vent	When time runs out in sterilizing mode, the vent valve opens. Steam / water are released back into the reservoir. The display changes as temperature and pressure in chamber changes.	FAST VENT XXX°F XX.X PSI
⚠	***Caution*** *Keep clear when M9/M11 door is ready to open! Failure to do so could result in severe burns from steam being released.*	
Door To Open (automatic) *Pertains only to M9/M11 UltraClave®*	An audible signal is emitted to indicate that the door is about to open. When pressure in chamber reaches zero, the door actuates to partially open (drying mode) position.	DOOR TO OPEN XXX°F XX.X PSI
Manual Door Open *Pertains only to M9D AutoClave*	An Audible signal is emitted when pressure inside chambers reaches zero to indicate Operator to open door. The door should be opened to the first stop (drying mode) position. The audible signal will continue to repeat every minute until either the door is opened to the DRY (partially opened) position, or by pressing the STOP button, aborting the DRY cycle.	OPEN DOOR TO DRY STOP TO ABORT
⚠	***Caution*** *The processed loads may still be wet if the Dry Cycle is aborted prior to completion. Always allow processed loads to dry in the sterilizer before they are handled to avoid re-contamination.*	
Drying	Time of Dry Cycle is counted down. If desired, the Dry Cycle can be aborted by pressing the STOP button.	DRYING MM:SS
	When Drying time reaches 0:00...	DRY CYCLE COMPLETE
Cycle Complete	An audible signal is emitted for 10 seconds.	SELECT CYCLE

Table 7-7
Design / Materials

Item	M9/M11 UltraClave and M9D AutoClave
Chamber Dimensions M9/M9D M11	 9” (22.9 cm) x 15” (38.1 cm) / Stainless Steel 11” (27.9 cm) x 18” (45.7cm) / Stainless Steel
Chamber Volume M9/M9D M11	0.47 ft^3 (13.4 L) 0.87 ft^3 (24.6 L)
Double Hinged Door (M9/M9D & M11)	Carbon Steel w/ Stainless Steel Liner
Door Latch M9/M11 M9D	Manual Double Bolt Latch w/Automatic Opening Manual Double Bolt Latch
Door Gaskets (M9/M9D & M11)	High Temperature Silicon Rubber
Trays M9/M9D M11	2 small (5.6”W x 12”L x .9”D) 2 large (7.3”W x 12”L x .9”D) *(Perforated Stainless Steel)* 2 small (6.6”W x 15”L x 1.1”D) 2 large (9”W x 15”L x 1.1”D) *(Perforated Stainless Steel)*
Tray Rack (M9/M9D & M11)	Formed Stainless Steel Sheet
Water Reservoir M9/M9D M11	Polyethylene Plastic - 1.1 gal (4.16 L) Polyethylene Plastic - 1.4 gal (5.3 L)
Water Fill System (M9/M9D & M11)	Gravity fill w/ Chamber Water Level Sensor
Water Fill Valve (M9/M9D & M11)	Electronic Solenoid
Heater (M9/M9D & M11)	1425 Watt Immersion Heater *(115 volt models)* 1500 Watt Immersion Heater *(230 volt models)*
Air Removal Valve (M9/M9D & M11)	Electronic Solenoid
Vent Valve (M9/M9D & M11)	Electronic Solenoid
Dry Cycle Features M9/M11 M9D *(All models incorporate an active drying system.)*	Door Automatically Opens Partially (Motor Driven) Manual Door (Operator manually opens door)

Indications for Use

“The Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and the Ritter M9D AutoClave® Automatic Sterilizer 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 on the following page for detailed information."

Standard Cycle Parameters

Cycle Type	Cycle Parameters			Drying Time	Items to be Sterilized *(Always consult the item manufacturer's recommendations for sterilization.)*
	Temp. (Min.)	Time	Press.[1] (Ref.)		
 Unwrapped	270°F (132°C)	3 min.	27.1 psi (186 kPa)	30 min.	• Instruments loose on a tray. • Open glass or metal canisters. • Tubing not used in surgical procedures. *(Max. length - 40" & Min. inside diameter - .187")* • Loose items manufacturers recommend for exposure at 270°F (132°C) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*
 Pouches	270°F (132°C)	4 min.	27.1 psi (186 kPa)	30 min.	• Pouched or loosely wrapped instruments. • Multiple layers of instruments separated by fabric. • Wrapped trays of loose instruments. • Wrapped cassettes. • Wrapped items manufactures recommend for exposure at 270°F (132°C) for 4 minutes.
 Packs	250°F (121°C)	30 min.	15 psi (104 kPa)	30 min.	• Textiles and surgical packs wrapped for sterilization. • Items, except liquids, manufacturers recommend for exposure at 250°F (121°C) for 30 minutes.
 Handpieces	270°F (132°C)	4 min.	27.1 psi (186 kPa)	30 min.	• Dental handpieces (wrapped or unwrapped). *Note: Verify acceptability of sterilization parameters with handpiece manufacturer.*

1. *The pressure shown in this table is for reference only. It's the ideal pressure of saturated steam at the sterilization temperature. The pressure shown on the sterilizer display may be higher.*

Description of Validated Loads

M9 Maximum Capacities			
Load Type	*Large Tray*	*Small Tray*	*Total*
Solid Instruments	2.4 lbs. (1089 grams) or	1.6 lbs. (726 grams) or	8.0 lbs. (3629 grams) or
Handpieces	2 handpieces with other instruments 2.4 lbs. (1089 grams) or	2 handpieces with other instruments 1.6 lbs. (726 grams) or	8 handpieces with other instruments 8.0 lbs. (3629 grams) or
Packs*	90 in3 ≤ 1.25 in. thick (1475 cm3 ≤ 3.2 cm thick)	55 in3 ≤ .75 in. thick (901 cm3 ≤ 1.9 cm thick)	290 in3 (4752 cm3)

M11 Maximum Capacities			
Load Type	*Large Tray*	*Small Tray*	*Total*
Solid Instruments	2.7 lbs., (1225 grams) or	1.8 lbs., (816 grams) or	9.0 lbs., (4082 grams) or
Handpieces	2 handpieces with other instruments 2.7 lbs. (1225 grams) or	2 handpieces with other instruments 1.8 lbs. (816 grams) or	8 handpieces with other instruments 9.0 lbs. (4082 grams) or
Packs*	145 in3 ≤ 1.5 in. thick (2376 cm3 ≤ 3.8 cm thick)	108 in3 ≤ 1.5 in. thick (1770 cm3 ≤ 3.8 cm thick)	505 in3 (8275 cm3)
**Allow a minimum of 1/4" (6.4 mm) space between each pack, and also from the chamber wall..*			

Technological Characteristics

The intended use, technological characteristics (i.e., design, material, energy source) principles of operation, safeguards, target population, and performance are the same for the proposed devices and their corresponding predicate devices.

Table 7-8
M9 Technological Characteristics Comparison

CHARACTERISTIC	PREDICATE MIDMARK M9 UltraClave	NEW MODELS MIDMARK & Ritter M9 UltraClave & Ritter M9D Autoclave
510(k) Clearance	K023348	K163337
Midmark Models #s	M9-02X & M9D-02X	M9-04X & M9D-042
Type of Steam Sterilizer	Tabletop Dynamic-Air-Removal (SFPP)	Same
Intended Use *(Same for all models)*	The M9 UltraClave™ is intended to 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	The Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and the Ritter M9D AutoClave® Automatic Sterilizer can be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable

	sterilization.	items (including dental handpieces) that are compatible with steam sterilization.
Indications for Use: (Cycle Comparison)	Parameters *(Sterilize Time/Temp./Dry Time[1])*	Parameters *(Sterilize Time/Temp./Dry Time)*
Unwrapped Cycle	3 min./ 270°F (132°C) / 30 min.	Same
Pouches Cycle	6 min./ 270°F (132°C) / 30 min.	4 min./ 270°F (132°C)/ 30 min.
Packs Cycle	30 min./ 250°F (121°C)/30 min.	Same
Handpiece Cycle	6 min./ 270°F (132°C) / 30 min.	4 min./ 270°F (132°C)/ 30 min.
Programmable 1	3-90 min./ 230-275°F / 30 min. (110-135°C)	N/A
Programmable 2	3-90 min./ 230-275°F / 30 min. (110-135°C)	N/A
Controls:		
Main Controller	Micro Processor Based Embedded Control	Same w/ Modifications to Incorporate a Real Time Clock (RTC) & Power Supply for New Printer Accessory
User Controls	Membrane Type Switches	Same
Temperature Sensor	Platinum RTD	Same
Pressure Sensor	PC Mounted Gauge Pressure Transducer	Same
Process Monitors:		
Display Type	LCD *(2 row x 20 character)*	Same
Operator Alerts	Audible Alarms & Visual Signals Displaying Status, Instructions & Self-Diagnostic Error Codes on LCD Display	Same
Printer Accessory *(Optional)*	5 VDC, 24 Character Dot Matrix Printer Records: Cycle Stats. - Time, Temp. & Press.	5 VDC, 24 Character Thermal Printer Records: Sterilizer ID, Date & Time in Addition to Cycle Stats. - Time, Temp. & Press.
Safety Features:		
Overpressure Protection	ASME press. relief valve (40 psi)	Same
Overheat Protection	Dual Auto-Reset Thermostats 450°F (232°C)	Same
Door Interlock	High Integrity Safety Switch	Same

Table 7-9
M11 Technological Characteristics Comparison

CHARACTERISTIC	PREDICATE MIDMARK M11 UltraClave	NEW MODELS MIDMARK & Ritter M11 UltraClave
510(k) Clearance	K990189	K163337
Midmark Models #s	M11-0XX	M11-04X
Type of Steam Sterilizer	Tabletop Gravity Displacement	Tabletop Dynamic-Air-Removal (SFPP)
Intended Use *(Same for all models)*	The M11 UltraClave is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable, reusable equipment. Dental handpieces can be sterilized in the M11 in the Pouches cycle. This device is not recommended for sterilization of liquids intended for direct patient contact.	The Midmark and Ritter M9 and M11 UltraClave® Automatic Sterilizers and the Ritter M9D AutoClave® Automatic Sterilizer 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.
Indications for Use: (Cycle Comparison)	Parameters *(Sterilize Time/Temp./Dry Time)*	Parameters *(Sterilize Time/Temp./Dry Time)*
Unwrapped Cycle	3 min./ 270°F (132°C) / 30 min.	Same
Pouches Cycle	15 min./ 270°F (132°C) / 30 min.	4 min./ 270°F (132°C) / 30 min.
Packs Cycle	30 min./ 250°F (121°C)/30 min.	Same
Liquids	30 min./ 250°F (121°C) / NA	N/A
Handpiece Cycle	N/A Cleared for Handpieces in Pouches Cycle	4 min./ 270°F (132°C) / 30 min.
Programmable 1	N/A	N/A
Programmable 2	N/A	N/A
Controls:		
Main Controller	Micro Processor Based Embedded Control	Similar w/ Improved Microcontroller & Modifications to Incorporate a Real Time Clock (RTC) & Power Supply for New Printer Accessory
User Controls	Momentary Tactile Switches	Momentary Membrane Switches

Temperature Sensor	Integrated-Circuit Temp. Sensor	Platinum RTD
Pressure Sensor	PC Mounted Gauge Pressure Transducer	Same
Process Monitors:		
Display Type	Array of 7 Segment Red LEDs	LCD *(2 row x 20 character)*
Operator Alerts	Audible Alarms & Visual Signals Displaying Status & Self-Diagnostic Error Codes	Audible Alarms & Visual Signals Displaying Status, Instructions & Self-Diagnostic Error Codes on LCD Display
Printer Accessory *(Optional)*	5 VDC, 24 Character Dot Matrix Printer Records: Cycle Stats. - Time, Temp. & Press.	5 VDC, 24 Character Thermal Printer Records: Sterilizer ID, Date & Time in addition to Cycle Stats. - Time, Temp. & Press.
Safety Features:		
Overpressure Protection	ASME press. relief valve (40 psi)	Same
Overheat Protection	Dual Auto-Reset Thermostats 295°F (146°C)	Dual Auto-Reset Thermostats 450°F (232°C)
Door Interlock	High Integrity Safety Switch	Same

TABLE 7-10
Specification & Certifications Summary

	M9 UltraClave / M9D Autoclave	**M11 UltraClave**
Physical Dimensions		
Overall Length w/Plug	20.38 in. (51.8 cm)	23.8 in. (60.5 cm)
Overall Width	15.3 in. (38.9 cm)	17.8 in. (45.2 cm)
Overall Height w/Printer	16.1 in. (40.9 cm)	18.1 in. (50.0 cm)
Required Counter Area	15.3 in. x 18 in. (38.9 cm x 45.7 cm)	17.8. x 21 in. (45.2 cm x 53.3 cm)
Chamber Size	9 in. dia. x 15 deep (22.9 cm x 38.1 cm)	11 in. dia. x 18 in. deep (27.9 cm x 45.7 cm)
Trays, Large (2)	7 5/16 in. x 12 in. x 7/8 in. (18.6 cm x 30.5 cm x 2.2 cm)	9 in. x 15 in. x 1 1/8 in. (22.9 cm x 38 cm x 2.9 cm)
Trays, Small (2)	5 5/8 in. x 12 in. x 7/8 in. (14.3 cm x 30.5 cm x 2.2 cm)	6 5/8 in. x 15 in. x 1 1/8 in. (16.8 cm x 38 cm x 2.9 cm)
Weights:		
Weight with Empty Reservoir	73 lbs. (33.1 kg)	99 lbs. (44.9 kg)
Weight with Shipping Carton	81 lbs. (36.7 kg)	131 lbs. (59.4 kg)

Water Reservoir Capacity	1.1 gal (4.16 L) Usable volume is 0.5 gallons (1.9 liters)	1.4 gal (5.3 L) Usable volume is 1.0 gallons (3.8 liters)
Electrical Rating:		
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 (± 10%), 12 Amp, 50/60 Hz	115 VAC (± 10%), 12 Amp, 50/60 Hz
230 Volt models	230 VAC (± 10%), 6.4 Amp, 50/60 Hz	230 VAC (± 10%), 6.4 Amp, 50/60 Hz
Fuse Ratings:		
115 VAC	F1....0.25 Amp, 250 V, Slo-blo, 1/4" x 1 1/4"	F1....0.25 Amp, 250 V, Slo-blo, 1/4" x 1 1/4"
	F2....15 Amp, 250 V, Fast Acting, 1/4" x 1 1/4"	F2....15 Amp, 250 V, Fast Acting, 1/4" x 1 1/4"
230 VAC	F1....0.125 Amp, 250 V, Slo-blo, 5 x 20 mm	F1....0.125 Amp, 250 V, Slo-blo, 5 x 20 mm
	F2....8 Amp, 250 V, Fast Acting, 5 x 20 mm	F2....8 Amp, 250 V, Fast Acting, 5 x 20 mm
Other Ratings:		
Chamber Press. Rating	40 psi (275.8 kPa)	40 psi (275.8 kPa)
Safety Valve Setting	40 psi (275.8 kPa)	40 psi (275.8 kPa)
Heat Emission	5000 BTU/hr. during operation	5000 BTU/hr. during operation
Operating Environment: Device approved for INDOOR USE ONLY		
Ambient Temp. Range	68°F to 104°F (+20°C to +40°C)	
Humidity	Less than 80% (non-condensing) (Pollution Degree 2, in accordance to IEC664)	
Operating Altitude	Less than 9842 ft. (3000m) above sea level	
Certifications:		
Midmark is an ISO 13485 and ISO 9001 Certified Company	ASME Boiler & Pressure Vessel Code, Section VIII, Div. 1	
	Canadian Registration Number: OH13037.541637908YTN; V0024.2	Canadian Registration Number: OH13037.541637908YTN; U9601.2
	UL61010-1, 2nd Edition	
	IEC 61010-2-040:2005, 1st Edition	
	CAN/CSA C22.2, No. 61010-1, 2nd Edition	
	CSA C22.2, No. 61010-2-040-07 Part 2-040, 1st Edition	
	ANSI/AAMI/IEC 62304	
	ANSI/AAMI ST55:2010/(R)2014	
	EMC: IEC 60601-1-2 Edition 4.0 2014-02 CISPR 11:2009, A1:2010 Class A, Group 1 IEC 61000-3-2:2014, Part 3-2 IEC 61000-3-3:2013, Part 3-3	

TABLE 7-11
List of Accessories

Accessory	M9 UltraClave / M9D Autoclave	M11 UltraClave
Speed-Clean, 1 bottle (16 oz.)	002-0396-00	002-0396-00
Speed-Clean, 1 Case (12 – 16 oz. bottles)	002-0396-05	002-0396-05
Thermal Printer	9A599001	9A599001
Horizontal Cassette Rack	N/A	9A215001
Vertical Cassette Rack	N/A	9A215002

Non-Clinical Performance Data

MIDMARK conducted validation studies in accordance with ANSI/AAMI ST55: 2010/(R)2014. Testing showed that the M9 and M11 UltraClave and the M9D AutoClave Self-Contained Steam Sterilizers meet all aspects of the standard, including physical and microbiological performance requirements.

Individual protocols were performed to validate the sterilization efficacy of each type of pre-programmed cycle of the proposed M9/M9D and M11 Self-Contained Steam Sterilizers.

Initially, temperature sensors were used to determine the thermal profile of the empty chamber. Testing was performed for all pre-programmed cycles for a total of three (3) full chamber runs for each pre-programmed cycle parameter.

Additionally, biological testing was conducted on fully loaded chambers. The sterility assurance level (SAL) of 10^{-6} was evaluated using the biological indicator (BI) overkill method. The SAL was achieved by inoculating the most difficult to sterilize locations with a minimum of 1.0×10^{6} spores of *Geobacillus stearothermophilus* and processing at one-half of the full cycle exposure time and evaluating the BIs for total BI lethality.

Clinical Performance Data

Clinical data was not required.

Other Information

None

Conclusion

The results from the validation studies and biological testing for the M9/M9D and the M11 demonstrates the subject devices are as safe, as effective, and performs as well or better than the predicate devices: M9/M9D-02X (K023348) and M11-00X (K990189)