K023348

MAR 0 3 2003

MIDMARK®

510(k) SUMMARY

The information required by 21 CFR § 807.92 is listed below.

Submitter: Midmark Corporation
60 Vista Drive
Versailles, OH 45380
(800) 633-0508

Contact Person: Gene Harshbarger
Regulatory & Quality Systems Administrator
(937) 526-8297
Fax: (937) 526-8316

Date Submitted: 10/2/02

Device Names:

M9-20X

Proprietary: Midmark M9 UltraClave™ Steam Sterilizer
Common: Steam Sterilizer
Classification: 80FLE: Sterilizer, Steam

Device to which the Midmark M9 UltraClave™ Steam Sterilizer claims equivalence:
Midmark M-11 UltraClave Steam Sterilizer with dental handpiece indications for use, cleared for marketing 4/19/99 on K990189

Device Description:
The Midmark M9 UltraClave™ Steam Sterilizer uses saturated steam at high pressures and temperatures to kill infectious bio-organisms. This steam is generated inside the sterilization chamber by an electric heating element. The sterilizer's electronic control system is pre-programmed to complete sterilization cycles according to established time, temperature, and pressure parameters.

Items to be sterilized are placed in the sterilization chamber. The operator chooses a sterilization cycle, and presses the appropriate switch. The sterilizer automatically admits a controlled volume of water to the chamber, heats the water into steam, sterilizes the items, and automatically vents the steam and dries the items after sterilization is complete.

Intended Use:
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 sterilization. Refer to Standard Cycle Parameters on the following page for detailed information.

Standard Cycle Parameters

PROGRAM	TEMP. (minimums)	TIME (minimums)	ITEMS TO BE STERILIZED *(Always consult the item manufacturer's recommendations for sterilization.)*
Unwrapped	270° F (132° C)	3 minutes	• Instruments loose on a tray. • Open glass or metal canisters. • Tubing not used in surgical procedures. • Loose items manufacturers recommend for exposure at 270°F (132°C).
Pouches	270° F (132° C)	6 minutes	• Pouched or loosely wrapped instruments. • Multiple layers of instruments separated by fabric. • Wrapped trays of loose instruments. • Tubing not used in surgical procedures. • Wrapped items manufacturers recommend for exposure at 270°F (132°C).
Packs	250° F (121° C)	30 minutes	• 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)	6 minutes	• Dental handpieces • Other complex lumened devices, manufacturers recommend for exposure at 270° F (132° C)
Programmable 1 & Programmable 2	User defined 230° F to 275° F (110° C to 135° C)	User defined 3 min. to 90 min.	• Items appropriate for the user defined parameters **CAUTION:** All material run in these cycles must be validated by the user. These programmable functions allow you to set different time and temperature parameters. It is important to properly coordinate sterilization temperature with cycle time. Permitted temperature range for proper sterilization is 250°-275°F (121°-135°C). Temperatures below 250°F (121°C) should only be used for disinfection.

Technological Characteristics Comparison:
The intended use, principles of operation, safeguards, energy sources, target population, and performance are the same for the proposed device and its predicate.

The physical design, control system, materials of construction, and method of manufacture differ slightly from the predicate device. The most significant difference is the use of an electronic air valve on the M9 UltraClave™ in place of the mechanical steam trap used on the predicate device to remove air from the chamber. This change allows for enhanced removal of air from the chamber. The electronic air valve is controlled via the embedded control system in response to the actual chamber conditions sensed by the temperature and pressure inputs. Thus, the air valve can be operated during the warm-up cycle as needed to remove air escaping from the sterilizer load late in the warm-up cycle to create a more ideal saturated steam environment. Both devices are designed to the appropriate industrial standards, and the M9 UltraClave™ meets performance standards that the predicate device does not.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

Mr. Gene Harshbarger
Regulatory & Quality Systems Administrator
Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380

Re: K023348
Trade/Device Name: Midmark M9 UltraClave™ Steam Sterilizer (M9-02X)
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: January 6, 2003
Received: January 7, 2003

Dear Mr. Harshbarger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K023348

Device Name: Midmark M9 UltraClave™ Steam Sterilizer (M9-02X)

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023348

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Programmable 2	User defined 230° F to 275° F (110° C to 135° C)	User defined 3 min. to 90 min.	• Items appropriate for the user defined parameters **CAUTION:** All material run in these cycles must be validated by the user. These programmable functions allow you to set different time and temperature parameters. It is important to properly coordinate sterilization temperature with cycle time. Permitted temperature range for proper sterilization is 250°-275° F (121°-135° C). Temperatures below 250°F (121°C) should only be used for disinfection.