

4/19/99

K 990189

h) 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: James Rile, Regulatory Coordinator
(937) 526-8797

Date Submitted: January 15, 1999

Device Names: Proprietary: Midmark M-11 Ultraclave Steam Sterilizer
Common: Steam Sterilizer
Classification: 80FLE: Sterilizer, Steam

Device to which the Midmark M-11 Ultraclave Steam Sterilizer with dental handpiece indications for use claims equivalence:

Midmark M-11 Ultraclave Steam Sterilizer, cleared for marketing 11/30/94 on K936181

Device Description:

The Midmark M-11 Ultraclave Steam Sterilizer uses saturated steam at high pressures and temperatures and 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, summarized below.

CYCLE	TEMPERATURE	PRESSURE	TIME
Unwrapped	132° C (270° F)	186 kPa (27 psi)	3 Minutes
Pouches	132° C (270° F)	186 kPa (27 psi)	15 Minutes
Liquids	121° C (250° F)	104 kPa (15 psi)	30 Minutes
Packs	121° C (250° F)	104 kPa (15 psi)	30 Minutes

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

Intended Use:

The M-11 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 M-11 in the Pouches cycle. This device is not recommended for sterilization of liquids intended for

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direct patient contact. Refer to Standard Cycle Parameters below for detailed information.

Indications for Use:

Standard Cycle Parameters

Cycle	Temp/Press/Time (minimums)	Items to be Sterilized (Always consult the item manufacturer's recommendations for sterilization.)
Unwrapped	132°C (270°F)/ 186 kPa (27 psi) 3 minutes	Instruments loose on a tray. Open glass or metal canisters. Tubing not used in surgical procedures. Items manufacturers recommend for exposure at 132°C (270°F) for 3 minutes. The sterility of unwrapped items is compromised on exposure to a non-sterile environment.
Pouches	132°C (270°F)/ 186 kPa (27 psi) 15 minutes	Instruments and dental handpieces. Loosely wrapped individual instruments. Multiple layers of instruments separated by fabric. Wrapped trays of loose instruments. Tubing not used in surgical procedures. Items manufacturers recommend for exposure at 132°C (270°F) for 15 minutes.
Liquids	121°C (250°F)/ 104 kPa (15 psi) 30 minutes	Liquids or gels that could boil over with rapid depressurization. Cycle includes special vent and dry functions. Not recommended for sterilization of liquids intended for direct patient contact.
Packs	121°C (250°F)/ 104 kPa (15 psi) 30 minutes	Textiles and surgical packs wrapped for sterilization. Items, except liquids, manufacturers recommend for exposure at 121°C (250°F) for 30 minutes.

To validate sterility claims for dental handpieces, which were not included in the predicate devices indications for use when it was cleared by the FDA, Midmark developed a new test protocol for the M-11. This protocol was designed to evaluate the M-11's ability to sterilize commercially available dental handpieces, when presented as a worst-case challenge. The resulting testing showed that, when used in accordance with Midmark's directions for use, the M-11 can sterilize dental handpieces to an acceptable SAL.

Technological Characteristics that differ between the Midmark M-11 Ultraclave Steam Sterilizer and its predicate device:

None. The intended use, principles of operation, physical design, control system, safeguards, energy sources, target population, materials of construction, method of manufacture, and performance are the same for the proposed device and its predicate.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 1999

Mr. James Rile
Regulatory Coordinator
Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380

Re: K990189
Trade Name: Modification Of: Midmark M-11 Ultraclave
Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: January 15, 1999
Received: January 20, 1999

Dear Mr. Rile:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

i) STATEMENT OF INDICATIONS FOR USE: K990189

Applicant: Midmark Corporation

Device Name: Midmark M-11 Ultraclave Steam Sterilizer

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)


 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number K990189

Prescription Use _____
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use X