K992744

510(k) SUMMARY

JAN 1 0 2000

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:

Mike Snyder
Regulatory Coordinator
(937) 526-8390

Date Submitted:

12/02/99

Device Names:

Proprietary: Midmark M4•9 EasyClave Steam Sterilizer
Common: Steam Sterilizer
Classification: 80FLE: Sterilizer, Steam

Device to which the Midmark M4•9 EasyClave 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 M4•9 EasyClave 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.

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 M4•9 EasyClave is to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable items (including dental handpieces) that are compatible with steam sterilization at 270°F. 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) 3:30 minutes	Instruments and dental handpieces loose on a tray. Open glass or metal canisters. Cassettes. Tubing not used in surgical procedures. Items that are compatible with a maximum temperature of 135°C (276°F). The sterility of unwrapped items is compromised on exposure to a non-sterile environment.
Wrapped	132°C (270°F)/ 186 kPa (27 psi) 9 minutes	Instruments and dental handpieces. Loosely wrapped individual instruments. Multiple layers of instruments separated by fabric. Wrapped trays of loose instruments. Wrapped cassettes. Tubing not used in surgical procedures. Items that are compatible with a maximum temperature of 135°C (276°F).

To validate sterility claims for dental handpieces, the M4•9 was tested to the same protocol used to validate these claims for the predicate device. The resulting testing showed that, when used in accordance with Midmark's directions for use, the M4•9 can sterilize dental handpieces to an acceptable SAL.

Technological Characteristics that differ between the Midmark M4•9 EasyClave Steam Sterilizer and its predicate device:
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. Both devices, however are designed to the appropriate industrial standards, and the M4•9 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

JAN 1 0 2000

Mr. Mike Snyder
Regulatory Coordinator
Midmark® Corporation
60 Vista Drive
Versailles, Ohio 45380

Re: K992744
Trade Name: Midmark M4•9 EasyClave Steam Sterilizer
Class: II
Product Code: FLE
Dated: December 2, 1999
Received: December 8, 1999

Dear Mr. Snyder:

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.

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,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE:

Applicant: Midmark Corporation

Device Name: Midmark M4•9 EasyClave Steam Sterilizer

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Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992744