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JUL - 7 2009

Midmark Corporation
M3 UltraFast™ Automatic Sterilizer
FDA 510(k) Submittal

510(k) Summary

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

Submitter:

Midmark Corporation
60 Vista Drive
PO Box 286
Versailles, OH 45380-0286

Contact Persons:

Gary Benning
R & D Engineer, Dental New Product Development
Phone: (937) 526-8357
Fax: (937) 526-8316
Email: gbenning@midmark.com

Gene Harshbarger
Regulatory and Quality Systems Manager
Phone: (937) 526-8297
Fax: (937) 526-8316
Email: gharshbarger@midmark.com

Date Submitted: 10Mar2009

Device Names:

Proprietary:	Midmark M3 UltraFast™ Automatic Sterilizer
Common:	Steam Sterilizer
Classification:	FLE: Sterilizer, Steam

Claimed Equivalence:

Company:	SciCan, Inc.
Product:	STAT*IM* 2000
510(k):	K915054

Claimed equivalence w/ respect to performance w/ similar cycle parameters:

Company:	SciCan, Inc.
Product:	STAT*IM* 7000
510(k):	K072466

Device Description:

The M3 UltraFast™ Automatic Sterilizer is a small table-top steam sterilizer that uses saturated steam at high temperature and pressure to kill infectious bio-organisms.

The device is composed of a water reservoir, an oscillatory pump, a small electric boiler, an ASME certified pressure vessel, surface heaters for drying, a removable door/tray assembly, an electric gear motor for opening and closing the door/tray, and a solenoid valve for venting. The

action of all of these components is coordinated by an integral proprietary design electronic control system, which includes a PC board, an LCD display, and a user interface membrane switch. The entire device is enclosed by a plastic and steel case. External to this device is a condensation tank, which is connected to the back of the unit, via a plastic tube.

Three different fully automatic pre-programmed sterilization cycles with parameters specific to the different load characteristics provide fast and easy use for efficient instrument processing. This sterilizer provides both audible and visual notification upon cycle completion and will dry the load in accordance with the CDC guidelines. A programmable dry cycle allows the user to customize the dry times from 20-60 minutes. This sterilizer has integrated technology to let the operator know if they have low water in the reservoir, or a full external condensing tank eliminating the need to continually monitor water levels.

Intended Use:

The Midmark M3 UltraFast™ Automatic Sterilizer can be used in medical, dental, and veterinary 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.

Differences in Intended Use from Predicate Devices:

The Midmark M3 UltraFast™ Automatic Sterilizer has three standard sterilization cycles, and all three of these cycles are capable of sterilizing dental handpieces (validated by third party efficacy testing). This differs from the predicate devices, the SciCan STAT*IM* 2000 and STAT*IM* 7000, which only have two of their three standard cycles approved for use with dental handpieces.

This difference in intended use does not affect the safety or effectiveness of the Midmark M3 UltraFast™ when used as labeled.

Technological Comparisons:

The design of the Midmark M3 UltraFast™ differs from the predicate device, the SciCan STAT*IM* 2000, in two key areas: The pressure vessel, and the method of drying.

1. **Pressure Vessel:** (This difference also applies to the STAT*IM* 7000 also)
   The predicate device, the STAT*IM* 2000, pressure vessel has an integral bulkhead for containing the forces generated by the steam. However, the liner of the pressure vessel responsible for containing the fluids (in their words, the "cassette") is removable. The operator, when loading and unloading the "cassette" full of instruments is actually inserting and removing the liner of the pressure vessel. Furthermore, this "cassette" is like a small metallic briefcase that the operator *manually* inserts into, and removes from, the unit.

   Like the SciCan STAT*IM* 2000, the Midmark M3 UltraFast™'s pressure vessel is rectangular. However, unlike the STAT*IM* 2000, five of the six walls of the pressure

vessel are integral to the M3 UltraFast™, with the door, or sixth wall, being removable. A light tray constructed of formed sheet metal is attached to this door. The operator loads the tray with items to be sterilized, and slides this door/tray assembly into the pressure vessel. Once a cycle is initiated, the unit *automatically* closes the door, via a set of claws that are attached to the bulkhead and that engage the door/tray assembly. This fixes the door tightly to the pressure vessel. Once sterilization has ended, the unit *automatically* opens the door, again by action of the claws attached to the bulkhead.

It should be noted here that the Midmark M3 UltraFast™'s pressure vessel meets the requirements of the current ASME Boiler and Pressure Vessel Code Section VIII, Division 1 and is stamped as such. The SciCan STAT*IM* 2000 pressure vessel is not currently certified to the ASME Boiler and Pressure Vessel Code.

2. **Method of Drying:**
   At the end of a sterilization cycle, when the steam has been vented from the chamber, the predicate device, the SciCan STAT*IM* 2000, begins drying its sterilized contents via an air pump arrangement which intakes air through a filter, pushes it through a boiler for warmth, then into the "cassette", and out through the tube that leads to the external condensation tank.

   By contrast, the Midmark M3 UltraFast™ has thin surface heaters attached to the outside of the integral pressure vessel which can warm the inside of the pressure vessel. Because the removable door of the M3 UltraFast™ is automatically opened and closed at the end of sterilization, the chamber can be opened to the outside atmosphere. This combination of warming the chamber with a clear path for moisture to escape is a very effective method for drying the sterile load.

Because of these design differences – that the M3 UltraFast™ has an automatic door opening mechanism, as opposed to a removable liner; that the M3 UltraFast™ uses surface heaters to dry the load, as opposed to forced air – the safeguards, physical design, and control systems are necessarily different from one another. However, the general performance of the two devices (the STAT*IM* 2000 and the M3 UltraFast™) once the chamber is closed, and through sterilization, is nearly identical to one another.

Non-Clinical Performance Data Summaries:

There are many similarities between the Midmark M3 UltraFast™ steam sterilizer, and its predicate devices, the SciCan STAT*IM* 2000 and STAT*IM* 7000, including its effectiveness at neutralizing micro-organisms.

In support of this claim, five studies were conducted on behalf of Midmark Corp. by a third party, SPSmedical Supply Corporation. These were:

1. A thermal profile of the chamber during normal operation
2. A total kill endpoint study using a micro-organism
3. Validation of the Unwrapped Cycle (Efficacy Test)
4. Validation of the Pouches Cycle (Efficacy Test)
5. Validation of the Low Temp Cycle (Efficacy Test)

The data for these tests are included in the 510(k) materials, proper. However, a brief summary of the results are submitted for your inspection:

1. Thermal Profile Study (SPS Document # 0604-46):

   Test Objective: To demonstrate that steady state thermal conditions are maintained when using the Midmark M3 UltraFast™ Sterilizer

   The results of thermal profile testing demonstrate that the Midmark M3 UltraFast™ Sterilizer can achieve and maintain steady state thermal conditions throughout all three preset cycles.

2. Total Kill Endpoint Testing (SPS Document # 0604-45):

   Test Objective: To demonstrate the total kill endpoint time of *Geobacillus stearothermophilus* spores when exposed to the Midmark M3 UltraFast™ Sterilizer. This data will be used for the development of the Unwrapped, Pouches, and Low Temp cycles.

   The results of this test were meant to serve as a starting point for development of the validation of the three preset cycles. Based on the results of this study, validation testing for the unwrapped cycle started with the following parameters:

Temperature:	132°C (270°F)
Half-Cycle Time:	1.75 minutes
Configuration:	Unwrapped
Maximum Load:	2.4 lbs. (1.09 kg)

3. Unwrapped Cycle Validation (SPS Document # 0604-47):

   Test Objective: To validate the Midmark M3 UltraFast™ Sterilizer Unwrapped Cycle for a 10^{-6} Sterility Assurance Level (SAL).

   Based on the results of this study, the Midmark M3 UltraFast™ Sterilizer is validated to a sterility assurance level (SAL) of 10^{-6} for the Unwrapped Cycle. Repetitive testing has shown the following full cycle parameters to be safe and effective when sterilizing loads of no more than 2.4 lbs., including handpieces:

Cycle Description:	Unwrapped
Temperature:	132°C (270°F)
Sterilization Time:	3.5 minutes

4. Pouches Cycle Validation (SPS Document # 0604-48):

Test Objective: To validate the Midmark M3 UltraFast™ Sterilizer Pouches Cycle for a 10^{-6} Sterility Assurance Level (SAL).

Based on the results of this study, the Midmark M3 UltraFast™ Sterilizer is validated to a sterility assurance level (SAL) of 10^{-6} for the Pouches Cycle. Repetitive testing has shown the following full cycle parameters to be safe and effective when sterilizing loads of no more than 2.4 lbs., including handpieces wrapped in a cassette:

Cycle Description:	Pouches
Temperature:	132°C (270°F)
Sterilization Time:	5.5 minutes

5. Low Temp Cycle Validation (SPS Document # 0604-49):

Test Objective: To validate the Midmark M3 UltraFast™ Sterilizer Low Temp Cycle for a 10^{-6} Sterility Assurance Level (SAL).

Based on the results of this study, the Midmark M3 UltraFast™ Sterilizer is validated to a sterility assurance level (SAL) of 10^{-6} for the Low Temp Cycle. Repetitive testing has shown the following full cycle parameters to be safe and effective when sterilizing loads of no more than 2.4 lbs., including handpieces wrapped in a cassette:

Cycle Description:	Low Temp
Temperature:	121°C (250°F)
Sterilization Time:	20 minutes

Performance Data Conclusions:

The Midmark M3 UltraFast™ Automatic Sterilizer has been independently proven to be capable of sterilizing a mixed load, no greater than 2.4 lbs., including handpieces, when used according to its labeling, and intended use statement.

The differences between the Midmark M3 UltraFast™, and its predicate devices, the SciCan STAT*IM* 2000 and STAT*IM* 7000 represent product improvements. The M3 UltraFast™ is as safe and effective, and performs as well or better than the SciCan STAT*IM* 2000 and STAT*IM* 7000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Midmark Corporation
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K090670
Trade/Device Name: Midmark M3 UltraFast™ Automatic Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: June 26, 2009
Received: July 1, 2009

Dear Mr. Kogoma:

This letter corrects our substantially equivalent letter of July 7, 2009.

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 (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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K090670

Device Name: Midmark M3 UltraFast™ Automatic Sterilizer

Indications for Use:

The Midmark M3 UltraFast™ Automatic Sterilizer can be used in medical, dental, and veterinary 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, in Table-1, on the following page, for detailed information:

Prescription Use ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090670

Table-1: M3's Intended Use: Cycles and Load Types

Cycle	Sterilization Parameters	Dry Time	Items to be Sterilized
 **Unwrapped**	Temperature: 270°F (132°C) Pressure: 27.1 PSI (186 kPa) Time: 3:30 minutes	Time: 40:00 minutes	• Dental instruments / handpieces loose on a tray or in an unwrapped cassette. • Other items manufacturers recommend for exposure at 270°F (132°C), loose on tray or in an unwrapped cassette.
 **Pouches**	Temperature: 270°F (132°C) Pressure: 27.1 PSI (186 kPa) Time: 5:30 minutes	Time: 40:00 minutes	• Dental instruments / handpieces in pouches, wrapped, or in a wrapped cassette. • Items manufacturers recommend for exposure at 270°F (132°C), in pouches, wrapped, or in a wrapped cassette.
 **Low Temp**	Temperature: 250°F (121°C) Pressure: 15.0 PSI (104 kPa) Time: 20:00 minutes	Time: 60:00 min.	• Rubber or plastic dental devices, dental instruments / handpieces loose on tray, in pouches, wrapped, or in a wrapped or unwrapped cassette. • Items manufacturers recommend for exposure at 250°F (121° C), loose on tray, in pouches, wrapped, or in a wrapped or unwrapped cassette.