K063681

SECTION 3:

JUN 29 2007

510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

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Summary Preparation Date: December 7, 2006

Device Names

Device Name: Tecno-Gaz ANDROMEDA VACUUM CS Autoclave

Classification Name: Sterilizer, Steam, Classified as Class II
Regulation number: 21 CFR 880.6880

Product Code: FLE

Predicate Devices

The Tecno-Gaz ANDROMEDA VACUUM CS Autoclave is substantially equivalent to the following devices:

- ✓ Midmark M9 Ultraclave Steam Sterilizer (K023348),
- ✓ Tuttnauer EHS Series Table top autoclave (K003470)
- ✓ Prestige Medical Series 2100 Clinical Autoclave (K962903)

Device Description

The Tecno-Gaz ANDROMEDA VACUUM CS autoclave is a table-top Steam Sterilizer and uses saturated steam at high pressures and temperatures to kill infectious bio-organisms. The steam is generated in the sterilization chamber by an electric heating element surrounding the chamber. Sterilization cycles are preprogrammed to complete each sterilization cycle according to the established times, temperature, and pressure parameter. These sterilization cycles are selected by an operator depending on the type of items to be sterilized.

The sterilizer automatically admits a controlled volume of water into the chamber, start heating process and steam generation, sterilizes the items. At the end of sterilization process the autoclave automatically vents the steam and dries the items.

Intended Use

Tecno-Gaz ANDROMEDA VACUUM CS Autoclave is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, and other facilities to sterilize heat and moisture-stable, reusable items (including dental hand pieces and and lumened devices) that are compatible with steam sterilization. Refer to Standard Cycle Parameters for detailed information.

Standard Cycle Parameters

CYCLES	TIME OF STERILIZATION	TIME OF DRYING	WORKING PRESSURE	MATERIALS	MAX. LOAD
C1 Not wrapped 134°C 273°F	6 minutes	17 minutes	220 kPa (32 psi)	- Metallic instruments	- 0.75 Kg (1.65 lb) every tray, at maximum 4 trays - 2.8 kg (6.17 lb) Whole full load
				- Unwrapped textile	- 0.5 Kg (1.1 lb) Whole full load
C2 Wrapped 134°C 273°C	11 minutes	17 minutes	220 kPa (32 psi)	- Metallic instruments	- 0.75 Kg (1.65 lbs) every tray, at maximum 4 trays - 2.8 kg (6.17 lbs) Whole full load
				- Dental handpieces	One handpiece per tray and no more than 3 trays as whole full load
				- Wrapped textile	- 0.5 Kg (1.1 lb) Whole full load
C3 Not wrapped 122°C 252°F	18 minutes	17 minutes	120 kPa (17 psi)	- Metallic instruments	- 0.75 Kg (1.65lbs) every tray, at maximum 4 trays - 2.8 kg (6.17lbs) Whole full load
				- Rubber or plastic devices (including lumened devices)	- 0.5 Kg (1.1 labs) every tray, at maximum 4 trays - 1,36 kg (2.99 lbs) Whole full load
				- Unwrapped textile	- 0.5 Kg (1.1 lb) Whole full load

C4 Wrapped 122°C 252°F	21 minutes	17 minutes	120 kPa (17 psi)	- Metallic instruments	- 0.75 Kg (1.65 lb) every tray, at maximum 4 trays - 2.8 kg (6.17 lb) Whole full load
				- Dental handpieces	One handpiece per tray and no more than 3 trays as whole full load
				- Rubber or plastic devices (including lumened devices)	- 0.5 Kg (1.1 labs) every tray, at maximum 4 trays - 1,36 kg (2.99 lbs) Whole full load
				- Wrapped textile	- 0.5 Kg (1.1 lb) Whole full load
C5 Not wrapped 134°C 273°F	6 minutes	2 minutes	220 kPa (32 psi)	- Metallic instruments	- 0.75 Kg (1.65 lb) every tray, at maximum 4 trays - 2.8 kg (6.17 lb) Whole full load

Comparison to Predicate Devices

The substantial equivalence comparison has been performed comparing the intended use, the technological characteristics and the cycle characteristics of the Tecno-Gaz Andromeda Vacuum CS to the predicate devices.

The intended use and the technological characteristics of the Tecno-Gaz Andromeda Vacuum CS and Midmark M9 Ultraclave Steam Sterilizer (K023348) are very similar, and both autoclaves conform to the same industrial standards.

Minor difference between Tecno-Gaz Andromeda Vacuum CS and predicate devices is further discussed in detail in Section 6. All process parameters and cycles are validated with performance tests according to the AAMI/ANSI ST55:2003 standards to assure that sterilization process is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Mediline Italia S.r.l.
C/O Mr. Maurizio Pantaleoni
Consultant
Alta Consulting LLC
6512 Bannockburn Drive
Bethesda, MD 20817

Re: K063681
Trade/Device Name: Tecno-Gaz ANDROMEDA VACCUM CS
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: June 15, 2007
Received: June 25, 2007

Dear Mr. Pantaleoni:

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.

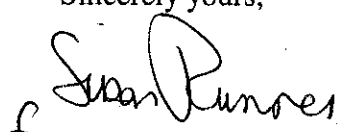
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 (240) 276- 0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K063681

Device Name: Tecno-Gaz ANDROMEDA VACUUM CS

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

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K063681

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