K032192

AUG 1 2 2004

510(k) Summary

Submitter: Tuttnauer USA Co. Ltd.
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Contact Name: Robert R. Basile

Date Prepared: July 15, 2003

Common Name: Electronic pre-vacuum autoclave

Trade Name: Tuttnauer pre-vacuum autoclave with vertical sliding door and steam generator, Models 4472 EP-1V and 5596 EP-1V

Classification Name: Steam Sterilizer
Class II Device - 21 C.F.R. § 880.6880

Substantial Equivalence:

The Tuttnauer Model 4472 EP-1V and 5596 EP-1V autoclaves are substantially equivalent to the following currently marketed sterilizer (which meets ANSI/AAMI ST-8):

Company	Product Name	510(k) Clearance Number
Tuttnauer USA Co. Ltd.	EHS Series Pre-vacuum Autoclaves	K003470

General Description:

The Tuttnauer Model 4472 EP-1V and 5596 EP-1V Autoclaves are steam sterilizers that provide onboard steam generation capability. They are designed for sterilization of heat stable medical devices; wrapped solids, hollow and porous products, as well as liquids for non-clinical applications in open or closed (but not sealed) containers. The sterilization medium is steam, which is directly introduced into the sterilization chamber. This eliminates the need to wait for water introduced into the chamber to boil and reach sterilization parameters.

Intended Use:

The Tuttnauer Model 4472 EP-1V and 5596 EP-1V autoclaves are intended to provide sterilization of heat stable medical devices; wrapped solids, hollow and porous products, as well as liquids for non-clinical applications in open or closed (but not sealed) containers.

Technological Characteristics:

The Tuttnauer Model 4472 EP-1V and 5596 EP-1V autoclaves are steam sterilizers that include as main components: a pressure vessel with steam jacket, heating elements, a chamber water reservoir, a water pump and a vacuum pump.

Characteristic	**Models 4472 EP-1V and 5596 EP-1V Autoclaves**	**EHS Series (K003470)**
Labeling/Intended Use	Auto Steam Autoclave	Auto Steam Autoclave
Process Parameters	Sterilization cycle defined by time, temp. and pressure	Sterilization cycle defined by time, temp. and pressure
Process Monitors	Temp. and pressure gauges, digital display screen, and printer	Temp. and pressure gauges, digital display screen, and printer
Pre-Vacuum	Yes	Yes
On-Board Steam Generation	Yes	Yes
Control	Cycle time, temp., pressure, and user interface controlled by microprocessor	Cycle time, temp., pressure, and user interface controlled by microprocessor
Program Comparison	Wrapped, unwrapped, liquids, and dry	Wrapped, unwrapped, and dry
Process Equivalent Times	Sterilization times of 3, 4, 10 or 30 minutes depending upon program selected	Sterilization times of 3.5, 8, or 30 minutes depending upon program selected

Non-Clinical Testing:

Tuttnauer conducted validation studies in accordance with ANSI/AAMI ST8 (2001). Testing showed that the sterilizers meet all aspects of the standard, including physical and microbiological performance requirements. Successful sterilization was accomplished in all tests performed.

Conclusion:

It is Tuttnauer USA Co. Ltd.'s conclusion that the Tuttnauer Models 4472 EP-1V and 5596 EP-1V Autoclaves are substantially equivalent to its predicate device. Based upon test data submitted, the Models 4472 EP-1V and 5596 EP-1V Autoclaves provide effective sterilization of instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Tuttnauer USA Company Limited
C/O Mr. Mark M. Yacura
Buchanan Ingersoll P.C.
1776 K Street, N.W. Suite 800
Washington, DC 20006-2365

Re: K032192
Trade/Device Name: Tuttnauer Pre-Vacuum Autoclave with Vertical Sliding Door and Steam Generator, Models 4472 EP-IV and 5596 EP-1V
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: June 18, 2004
Received: June 18, 2004

Dear Mr. Yacura:

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,

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): K032192

Device Name: Tuttnauer Pre-Vacuum Autoclave with Vertical Sliding Door and Steam Generator, Models 4472 EP-1V and 5596 EP-1V

Indications For Use: The Models 4472 EP-1V and 5596 EP-1V autoclaves are intended to provide sterilization of heat stable medical devices; wrapped solids, hollow and porous products, as well as liquids (for non-clinical application only) in open or closed (but not sealed) containers. It has the following automated program sterilization cycles:

Program 1 (Flash - Porous)

Parameters:

- Sterilization temperature & Range: 270°F (270 - 276°F)
- Sterilization time: 3 minutes
- Pressure & Range: 186 Kpa (186 - 220 kPa); 12.3 psig (12.3 - 17.2 psig)
- Maximum load: two (2) 16 lb. unwrapped trays (per ST8:2001)

Program 2 (Flash - Nonporous)

Parameters:

- Sterilization temperature & Range: 270°F (270 - 276°F)
- Sterilization time: 10 minutes
- Pressure & Range: 186 kPa (186 -220 kPa); 12.3 psig (12.3 - 17.2 psig)
- Maximum load: two (2) 16 lb. unwrapped trays (per ST8:2001)

Program 3 (Wrapped - 270°F)

For sterilization of wrapped instruments, utensils, textiles and materials which the manufacturer recommends autoclaving at temperatures of up to 270°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 270°F (270 - 276°F)
- Sterilization time: 4 minutes
- Dry time: 30 minutes
- Pressure & Range: 186 kPa (186 - 220 kPa); 12.3 psig (12.3 - 17.2 psig)
- Maximum load: two (2) 16 lb. wrapped trays or 8 towel packs (per ST8:2001)

Program 4 (Wrapped - 270°F)

For sterilization of wrapped instruments, utensils, textiles and materials which the manufacturer recommends autoclaving at temperatures of up to 270°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 270°F (270 - 276°F)
- Sterilization time: 10 minutes
- Dry time: 20 minutes
- Pressure & Range: 186 kPa (186 - 220 kPa); 12.3 psig (12.3-17.2 psig)
- Maximum load: two (2) 16 lb. wrapped trays or 8 towel packs (per ST8:2001)

Program 5 (Wrapped 275°F)

For sterilization of wrapped instruments, utensils, textiles and materials which the manufacturer recommends autoclaving at temperatures of up to 275°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 275°F (275 - 281°F)
- Sterilization time: 3 minutes
- Dry time: 20 minutes
- Pressure & Range: 214 kPa (214 - 245 kPa); 16.3 psig (16.3 – 20.8 psig)
- Maximum load: two (2) 16 lb. wrapped trays or 8 towel packs (per ST8:2001)

Program 6 (Wrapped - 250°F)

For sterilization of wrapped instruments, utensils, textiles and materials which the manufacturer recommends autoclaving at temperatures of up to 250°F with drying cycle.

Parameters:

- Sterilization temperature & Range: 250°F (250 - 256°F)
- Sterilization time: 30 minutes
- Dry time: 45 minutes
- Pressure & Range: 103 kPa (103-128 kPa); 0.2 psig (0.2 – 3.9 psig)
- Maximum load: two (2) 16 lb. wrapped trays or 8 towel packs (per ST8:2001)

Program 7 (Liquids - 250°F) For non-clinical applications only

For sterilization of liquids which the manufacturer recommends autoclaving at temperatures of up to 250°F. For non-clinical applications only.

Parameters:

- Sterilization temperature & Range: 250°F (250 - 256°F)
- Sterilization time: 30 minutes
- Pressure & Range: 103 kPa (103 - 128 kPa); 0.2 psig (0.2 – 3.9 psig)
- Maximum load: three (3) 1 liter flasks (per ST8:2001)

Program 8 (Bowie-Dick Test)

This is a test program, with fixed sterilization parameters of 273°F and 3.5 minutes which cannot be modified by the operator.

Parameters:

- Sterilization temperature & Range: 273°F (273-274°F)
- Sterilization time: 3.5 minutes
- Dry time: 2 minutes
- Pressure & Range: 207 kPa (207 Kpa); 15.3 psig (15.3 psig)

Program 9 (Air Leakage Test)

This test is intended to test air leakage to the chamber through the door seal or any other seals. This test is performed in vacuum phase.

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

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