K063711

510(k) Summary

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Submitter:	Tuttnauer USA Co. Ltd. 25 Power Drive Hauppauge, NY 11788 Phone: 631-737-4850 Fax: 631-737-0720
Contact Name:	Robert R. Basile, V.P.
Date Prepared:	November 21, 2006
Common Name (for all):	Electronic pre-vacuum autoclave, steam sterilizer
Trade Names:	Tuttnauer Prevacuum Steam Heated Autoclave with Automatic Hinged Door (Model 6990 SP-1A) Tuttnauer Prevacuum Steam Heated Autoclave with Automatic Hinged Door (Model 66120 SP-1A) Tuttnauer Prevacuum Steam Heated Autoclave with Two Automatic Hinged Doors (Model 69150 SP-2A) Tuttnauer Prevacuum Steam Heated Autoclave Equipped with Two Automatic Hinged Doors (Model 69120 L USA SP-2A) Tuttnauer Steam-Heated Prevacuum Autoclave with Two Horizontal Sliding Doors (Model 69180 SP-2HA) Tuttnauer Prevacuum Steam Heated Autoclave Equipped with Vertical Sliding Door (Model 6690 L USA SP-1V)
Classification Name (for all):	Steam Sterilizer Class II Device - 21 C.F.R. § 880.6880

Substantial Equivalence:

All six Tuttnauer autoclave models referenced above (Models 6990 SP-1A; 66120 SP-1A; 69150 SP-2A; 69120 L USA SP-2A; 69180 SP-2HA; and 6690 L USA SP-1V) are claimed to be substantially equivalent to the autoclaves cleared under the following 510(k) numbers:

K850264 (non-computer controlled autoclaves)
K850264A (non-computer controlled autoclaves)
K032192 (computer controlled autoclaves)

The six Tuttnauer autoclave models covered by this 510(k) notification differ in the size of their chambers (dimensions and volume) and in their door configurations. All six models have been previously cleared by FDA in their manual form; the six models covered herein only differ from these previously cleared devices in that they contain electronic control panels to allow for automatic usage. As there is no change to factors affecting sterilization, such as cycle time, temperature, or pressure, these six devices should be equivalent to the predicate devices cleared under the three 510(k) numbers listed above.

General Description:

Tuttnauer autoclave models 6990 SP-1A; 66120 SP-1A; 69150 SP-2A; 69120 L USA SP-2A; 69180 SP-2HA; and 6690 L USA SP-1V are all prevacuum autoclaves that utilize saturated steam as the sterilizing agent. Each of these autoclaves is 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 key differences between the six models covered by this 510(k) notification are (1) chamber dimensions/chamber volume, and door configuration. These differences are summarized here:

Model	Chamber Dim. (w x h x d)	Chamber Volume	Door Configuration
6990 SP-1A	24" x 36" x 36"	21 ft.^{3}	automatic hinged door driven by pneumatic drive
66120 SP-1A	26" x 26" x 50"	21.2 ft.^{3}	automatic hinged door driven by pneumatic drive
69150 SP-2A	24" x 36" x 60"	33 ft.^{3}	two automatic hinged doors driven by pneumatic drive
69120 L USA SP-2A	24" x 36" x 48"	750 l.^{3}	two automatic hinged doors driven by pneumatic drive
69180 SP-2HA	24" x 36" x 83"	1165 l.^{3}	two horizontal sliding doors operated by hydraulic system

			through an oil cylinder
6690 L USA SP-1V	26" x 26" x 39"	450 l.[3]	one vertical sliding door operated by hydraulic system through two oil cylinders mounted laterally on both sides of door

The six Tuttnauer models covered herein are substantially the same as models cleared under 510(k) numbers K850264 and K850264A. Both of these 510(k) notifications and clearances cover the manual versions of the automatic autoclaves subject to this 510(k) application. Tuttnauer has modified the control panel of the manual autoclaves, replacing the current manual control panel with an electronic control panel. CDRH has already cleared a similar manual-to-electronic change in 510(k) number K032192. Therefore, all three of these 510(k) notifications and subsequent clearances are claimed as predicate devices for all six of the autoclaves in this 510(k) application.

Design and Materials:

Each of the six Tuttnauer autoclave models is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a water reservoir, a water pump, and a vacuum pump. Each autoclave is pre-programmed with twelve sterilization cycles, and each has two test programs: (1) a "Bowie & Dick Test," and (2) an "Air Leakage Test." The six autoclaves are equipped with the capability to shut down automatically. An emergency stop push button that is mounted on the front panel is an available option for customers with specific needs.

The control software, which is identical to that used in the autoclaves cleared under K032192, allows for automatic operation of all six autoclaves. The microcomputer technology employed in the autoclaves ensures that the entire cycle will operate on a fully-automatic basis. Therefore, no further intervention is necessary after setting the pre-selected parameters and starting operation of the autoclave.

Comparison to Cleared Devices:

The only material component that is being changed on these six devices is the substitution of a manual control panel with an electronic control panel, including operational software. This electronic control panel/operational software package was previously cleared as a modification to two existing Tuttnauer autoclaves under 510(k) number K032192. This control panel/software substitution does not affect the intended use of the six devices included in this notification, and the fundamental scientific technology of the six devices is not altered.

Intended Use:

All six Tuttnauer autoclave models referenced above (Models 6990 SP-1A; 66120 SP-1A; 69150 SP-2A; Model 69120 L USA SP-2A; 69180 SP-2HA; and Model 6690 L USA SP-1V) 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. Indication for use statement is attached

Because of the difficulty to standardize the liquid cycle load. This cycle in not intended for sterilization of materials that come into contact with patients and should only be used for non-clinical applications only.

Technology Considerations:

Each of the six Tuttnauer autoclave models is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a water reservoir, a water pump, and a vacuum pump.

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:

For all of the foregoing reasons, Tuttnauer believes that the six Tuttnauer autoclave models described in this 510(k) notification may be safely marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tuttnauer Company Limited
C/O Mr. Mark Yacura
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1776 K Street N.W., Suite 300
Washington, DC 20006-2365

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Re: K063711
Trade/Device Name: Tuttnauer Prevacuum Steam Heated Autoclaves Models 6990 SP-1A, 66120 SP-1A, 69150 SP-2A, 69120 L USA SP-2A, 69180 SP-2HA, 6690 L USA SP-1V
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 13, 2006
Received: December 14, 2006

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 (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: K063711

Device Name: Tuttnauer Prevacuum Steam Heated Autoclaves models 6990 SP-1A, 66120 SP-1A, 69150 SP-2A, 69120 L USA SP-2A, 69180 SP-2HA, 6690 L USA SP-1V

Indications for Use: This Tuttnauer autoclave is designed for use in healthcare settings for the sterilization of heat stable medical devices; wrapped solids, hollow and porous products. Sterilization of liquid loads should only be used in non-clinical applications in open or closed (but not sealed) containers.

Maximum loads depend upon the chamber size, and are listed below.

MODEL NUMBER 6990 SP-1A

CHAMBER (inches) 24x36x36

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	72	2
03, 04	Unwrapped	270/274	72	2
05, 06, 08	Wrapped	270	72	2
07	Wrapped	274	72	2
09, 10, 11, 12	Liquids	250	72	2
13	B & D test	274	72	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave

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)

[signature]

[illegible], General Hospital, Infection Control, Devices

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MODEL NUMBER 66120 SP-1A

CHAMBER (inches) 26x26x50

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	96	2
03, 04	Unwrapped	270/274	96	2
05, 06, 08	Wrapped	270	96	2
07	Wrapped	274	96	2
09, 10, 11, 12	Liquids	250	96	2
13	B & D test	274	96	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave

MODEL NUMBER 69150 SP-2A

CHAMBER (inches) 24x36x60

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	192	2
03, 04	Unwrapped	270/274	192	2
05, 06, 08	Wrapped	270	192	2
07	Wrapped	274	192	2
09, 10, 11, 12	Liquids	250	192	2
13	B & D test	274	192	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave

MODEL NUMBER 69120 SP-2A

CHAMBER (inches) 24x36x48

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	192	2
03, 04	Unwrapped	270/274	192	2
05, 06	Wrapped	270	192	2
07	Wrapped	274	192	2
08	Wrapped	250	192	2
09, 10, 11, 12	Liquids	250	192	2
13	B & D test	274	192	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave

MODEL NUMBER 69180 SP-2HA

CHAMBER (inches) 24x36x83

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	256	2
03, 04	Unwrapped	270/274	256	2
05, 06	Wrapped	270	256	2
07	Wrapped	274	256	2
08	Wrapped	250	256	2
09, 10, 11, 12	Liquids	250	256	2
13	B & D test	274	256	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave

MODEL NUMBER 6690 SP-1V

CHAMBER (inches) 26x26x39

Cycle Number	Program	Temperature °F	Maximum Load (lbs)	Maximum Trays
01, 02	Unwrapped	250	144	2
03, 04	Unwrapped	270/274	144	2
05, 06, 08	Wrapped	270	144	2
07	Wrapped	274	144	2
09, 10, 11, 12	Liquids	250	144	2
13	B & D test	274	144	2
14	Air leak test	-	-	-

Maximum load for one tray may not exceed the maximum load for the autoclave