K962282

510(k) Summary

NOV 12 1997

Submitter:

Tuttnauer USA Co. LTD.
33 Comac Loop
Equi Park
Ronkonkoma, New York 11779

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Contact Name: Robert R. Basile, V.P.

Date Prepared: June 13, 1997

Common Name: Pre-Vacuum autoclave, table-top steam sterilizer

Trade Name: Tuttnauer Model EPV Pre-vacuum Autoclave

Classification Name:

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

Substantial Equivalence:

The Tuttnauer Model EPV series Pre-vacuum autoclave is claimed to be substantially equivalent in safety and effectiveness to the Tuttnauer Model E series autoclave that is currently approved and legally marketed under 510(k) number K920478. The Model EPV series is an improvement of the basic E Model through incorporation of a vacuum pump and minor modification of the software driver to narrow the sterilization temperature control range.

General Description:

The Tuttnauer Model EPV series autoclave is a table-top steam sterilizer that includes as its main components a vacuum pump, water reservoir, heat source and sealed chamber. As with the predicate device, the EPV has three pre-programmed sterilization cycles, one user definable cycle and a Bowie-Dick test cycle. The three pre-programmed cycles are for unwrapped instruments (134°C at 3 minutes), wrapped instruments (134°C at 7 minutes) and liquids (121°C at 30 minutes).

The Model EPV autoclave is produced in two sizes, the 2340EPV with a chamber size of 9" x 18.5" and the 2540EPV with a chamber size of 10" x 18.7".

Design and Materials:

The pressure chamber, door and locking device are constructed from stainless steel. The pressure chamber, and components are designed, tested and stamped for conformance to ASME code.

A microprocessor controls the cycle parameters. The software provides the microprocessor with the necessary information to control the device within its desired parameters. The software has been validated to ensure compliance with all applicable requirements.

Intended Use:

The Model EPV is intended to provide sterilization of medical and dental instruments and to sterilize liquids for non-clinical applications.

Technology Considerations:

With the exception of the addition of a vacuum pump, the Model EPV series exhibits the same technological characteristics as the Model E, its predicate device. All of the components that may be found in the Model E are present in the Model EPV.

The addition of a pre-vacuum cycle to the sterilization program increases the efficiency of the device through removal of air pockets from packs and porous loads, allowing better steam penetration into the packs. The addition of a vacuum pump also provides better drying of sterilized material at the end of the cycle by creating a vacuum in the chamber to increase evaporation.

The software driver for the EPV has been modified in relation to the code for the Model E to take into account the addition of a pre-sterilization vacuum stage and post-sterilization vacuum drying. The software has also been modified to narrow the chamber temperature control specifications in line with European requirements.

Safety and Effectiveness:

Evaluations have been completed to validate the safety and effectiveness of these devices. Testing was completed using half-cycle and total kill endpoint analysis. The sterilizers were also tested under in-use, worst-case and simulated use conditions. The EPV rendered all recommended loads sterile on half-cycle and all other testing was completed successfully.

The Tuttnauer Model EPV complies with domestic and international safety standards including Underwriter's Laboratories UL 544, Canadian Standards Association (CSA) medical device standards, European TUV standards and Japanese safety standards. The pressure chamber complies with ASME standards for pressure vessels and Canadian CRN requirements.

Conclusion:

It is Tuttnauer USA Co. Ltd.'s conclusion that the Model EPV series autoclave is substantially equivalent to its predicate device, the Tuttnauer Model E series autoclave, 510(k) number K920478. Based upon the test data submitted, the Model EPV provides effective sterilization of recommended loads within the recommended cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

Mr. Robert R. Basile
Vice President
Tuttnauer USA Co. Ltd.
33 Comac Loop, Equi-Park
Ronkonkoma, New York 11779

Re: K962282
Trade Name: Tuttnauer Prevacuum Table Autoclave
Regulatory Class: II
Product Code: FLE
Dated: October 31, 1997
Received: October 31, 1997

Dear Mr. Basile:

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

510(k) Number: K962282

Device Name: Tuttnauer Models 2340 and 2540 "EPV" Series Table-top Pre-Vacuum Autoclave

Indications For Use: Tuttnauer electronic controlled pre-vacuum autoclaves are intended to be used for sterilization of solid metal instruments, solid metal hinged instruments and other materials that will withstand temperatures and pressure required for sterilization.

The sterilizers have 5 cycles: unwrapped instruments (134°C at 3 minutes and 29 psi); wrapped instruments (134°C at 7 minutes and 29 psi); liquids (121°C at 30 minutes and 16 psi); Bowie Dick test program (134°C at 3.5 minutes and 29 psi); and a free program with adjustable sterilization times and temperatures. With the exception of the free program, all of these cycles are pre-programmed, requiring no user input. The free program allows the user to select their own sterilization parameters, however, the operations manual warns that sterilization has not been validated for user selected settings, and cautions the user that they must validate sterilization.

These autoclaves are intended for use in ophthalmic, dental and medical clinics, first aid rooms, and small laboratories in conformity with 21 C.F.R. § 880.6880.

(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 Dental, Infection Control,
and General Hospital Devices

510(k) Number _____

Prescription Use _____ OR Over -The-Counter Use _____

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)