

510(K) Summary

K973550

Submitter:

Tuttnauer USA Co. LTD.
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Ronkonkoma, New York 11779

OCT 29 1997

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

Date Prepared: September 18, 1997

Common Name: Autoclave, table-top steam sterilizer

Trade Name: Tuttnauer Manual Autoclave Models (M, MK, MP).

Classification Name:

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

Substantial Equivalence:

The Modified Tuttnauer Model M series autoclave is claimed to be substantially equivalent in safety and effectiveness to the Tuttnauer Model M series autoclave that is currently cleared and legally marketed under 510(k) number K833837. With the exception of the change from a ball-type thrust bearing to a solid type thrust bearing in the door closure mechanism, the modified devices are identical to the Model M cleared under K833837.

General Description:

The Tuttnauer Model M series autoclave is a table-top steam sterilizer that includes as its main components a multi-valve control assembly & timer, water reservoir, heat source and sealed chamber. The M can sterilize unwrapped instruments (134°C at 3 minutes), wrapped instruments (134°C at 7 minutes) and liquids (121°C at 30 minutes).

The Model M autoclave is produced in four sizes, the 1730 with a chamber size of 7" x 12"; the 2340 with a chamber size of 9" x 18.5" and the 2540 with a chamber size of 10" x 18.7". The 3870, which has a chamber size of 15" x 27", is not subject to this corrective action.

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.

Intended Use:

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

Technology Considerations:

The modified Model M exhibits the same technological characteristics as the Model M, its predicate device. With the exception of a solid thrust bearing, all of the components that may be found in the unmodified Model M are identical to those in the modified version.

Safety and Effectiveness:

Because modification of the thrust bearing on the door closure mechanism does not effect the autoclave's sterilization parameters, the modified Model M series presents an identical sterilization profile.

The Tuttnauer Model M 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. Additionally, each pressure vessel is individually tested for conformance prior to release.

Conclusion:

It is Tuttnauer USA Co. Ltd.'s conclusion that the modified Model M series autoclave is substantially equivalent to its predicate device, the Tuttnauer Model M series autoclave, 510(k) number K833837. Based upon the engineering calculations and ASME testing, the modification to the door closure assembly provides safe operation for these devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tuttnauer USA Company, Ltd.
C/O Mr. Mark M. Yacura
Akin, Gump, Strauss, Hauer & Feld, L.L.P.
1333 New Hampshire Avenue, N.W., Suite 400
Washington, DC 20036

OCT 29 1997

Re: K973550
Trade Name: Tuttnauer Table-Top Autoclaves, Models 1730,
2340 and 2540 "M" and "E" Series
Regulatory Class: II
Product Code: FLE
Dated: September 18, 1997
Received: September 18, 1997

Dear Mr. Yacura:

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.

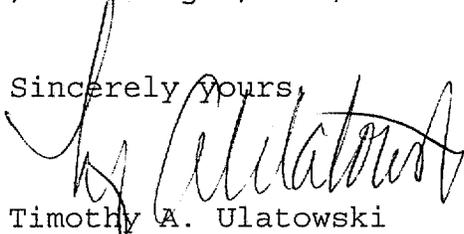
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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: K973550

Device Name: Tuttnauer Models 1730, 2340 and 2540 "M" and "E" Series Table-top Autoclave

Indications For Use: Tuttnauer electronic and manual controlled 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 3 cycles: unwrapped instruments (134°C at 3 minutes and 29 psi); wrapped instruments (134°C at 7 minutes and 29 psi); and liquids (121°C at 30 minutes and 16 psi). In the "E" Series, these cycles are pre-programmed, whereas in the "M" Series the user must manually set the parameters, however, these parameters are recommended in the labeling.

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)

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973550

Prescription Use _____ OR Over-The-Counter Use X

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)