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K993856

510(K) SUMMARY

Submitter: Tuttnauer USA Co. Ltd.
33 Comac Loop, Equi-Park
Ronkonkoma, NY 11779

Phone: 800-624-5836
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Contact Name: Robert R. Basile

Date Prepared: October 25, 1999

Common Name: Electronic autoclave, table-top steam sterilizer

Trade Name: Tuttnauer Electronic Autoclave Models (E, EA, EK, EP, EKA)

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

Substantial Equivalence:

The modified Tuttnauer E Series Electronic Table-top Autoclave is substantially equivalent to the following currently cleared and legally marketed autoclave:

Company	Product Name	510(k) Clearance Number
Tuttnauer USA Co. Ltd.	E Series Electronic Autoclave	K920478

With the exception of changes to the automated program cycle times and the labeling to allow sterilization of dental handpieces, the modified devices are identical to the Model E cleared under K920478.

General Description:

The Tuttnauer Model E series autoclave is a table-top steam sterilizer that includes as its main components an electronic control, water reservoir, heat source and sealed chamber. The E has three pre-programmed sterilization cycles. The three pre-programmed cycles are for unwrapped instruments (134°C at 4 minutes), wrapped instruments (134°C at 8 minutes) and liquids (121°C at 30 minutes). Dental handpieces can be sterilized as unwrapped or wrapped instruments without modification to cycle times or temperatures.

The Model E 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"; the 2540 with a chamber size of 10" x 18.7"; and the 3870, which has a chamber size of 15" x 27."

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 Tuttnauer E Series Electronic Table-top Autoclave is intended to provide sterilization of medical and dental instruments (including dental handpieces) and to sterilize liquids for non-clinical applications.

Technology Considerations:

The modified E Series exhibits the same technological characteristics as the Tuttnauer E Series Electronic Table-top Autoclave, its predicate device. All of the components that may be found in the unmodified Model E are identical to those in the modified version.

Non-Clinical Testing:

Tuttnauer conducted validation studies on the E Series Electronic Table-top Autoclave to ensure effective handpiece sterilization. Representative handpieces from various manufacturers were inoculated in their most difficult to sterilize areas for the testing. Worst-case handpiece loads were then determined for the sterilizer. Three half-cycle tests were performed for each of unwrapped and wrapped methods of sterilization. The testing shows that dental handpieces may be effectively sterilized in the E Series Electronic Table-top Autoclave.

Conclusion:

It is Tuttnauer USA Co. Ltd.'s conclusion that the modified Tuttnauer E Series Electronic Table-top Autoclave is substantially equivalent to its predicate device. Based upon test data submitted, Tuttnauer E Series Table-top autoclaves effectively sterilize up to 5 dental handpieces contained within them during normal autoclave operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tuttnauer USA Company Limited
C/O Mr. Mark M. Yacura
Buchanan Ingersoll, P.C.
1776 K Street, Northwest Suite 800
Washington, DC 20006-7910

Re: K993856
Trade Name: Tuttnauer Models 1730, 2340, 2540 and 3870 "E" Series Table-top Autoclave
Regulatory Class: I
Product Code: FLE
Dated: January 26, 2001
Received: January 26, 2001

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 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). 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 Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A.Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Tuttnauer Models 1730, 2340, 2540 and 3870 "E" Series Table-top Autoclave

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

The sterilizers have 3 cycles: unwrapped instruments (134°C at 4 minutes and 29 psi); wrapped instruments (134°C at 8 minutes and 29 psi); and liquids (121°C at 30 minutes and 16 psi). These cycles are pre-programmed and are recommended in the labeling.

Tuttnauer E Series Electronic Table-top 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)

Prescription Use _____ OR Over -The-Counter Use X

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993856