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510(k) Summary

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

Date Prepared: June 14, 2011

Common Name: Electronic autoclave, steam sterilizer

Trade Name: Tuttnauer EZ Plus Series Electronic Tabletop Autoclaves (EZ9 Plus, EZ11 Plus, and EZ 15 Plus)

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

Substantial Equivalence:

The Tuttnauer autoclaves that are the subject of this 510(k) (EZ Plus Series autoclaves) are claimed to be substantially equivalent to the autoclaves cleared under K090783, K063711, K021504, and K993856. These predicate devices are equivalent in chamber size and general operation principles. The door design and software for the EZ Series autoclaves have been changed. The nominal parameters (*e.g.,* sterilization temperature and time; dry time; and maximum/average cycle times) are not identical to those for the predicate devices, but follow ANSI/AAMI guidelines. The EZ Plus autoclaves and all predicate devices use steam as the sterilization agent.

General Description:

The EZ Plus autoclaves are autoclaves designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (*e.g.,* dental hand pieces; suction pipes) in ophthalmic, dental, and medical clinics; in first aid rooms; and in small laboratories. The device uses electrically generated heat to produce steam as the sterilizing agent. The device is equipped with multiple safety features. The door containing a safety locking mechanism that does not permit operation unless the door is closed, and does not permit the door to be opened until the internal chamber pressure is at atmospheric pressure. Additional EZ Plus safety features include an automatic safety shutoff to prevent chamber overheating; two (2) thermostats to detect overheating of the generator and the chamber; and a safety pressure valve for the pressure vessel. A digital display is used for monitoring and control purposes. There is an optional printer available to record cycle parameters.

Only United States Food and Drug Administration cleared accessories such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes should be used with this autoclave.

Design and Materials:

The EZ Plus Series autoclaves are steam sterilizer composed of a sterilization chamber, electronic heating elements, a clean water reservoir, housing, and control system. The EZ Plus Series is electronically controlled, and includes four pre-programmed sterilization cycles. All components in the sterilization path are constructed of grades of stainless steel that are deemed acceptable for steam sterilizers.

Indications for Use: The EZ Plus Series autoclaves are autoclaves designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (*e.g.*, dental hand pieces; suction pipes) in ophthalmic, dental, and medical clinics; in first aid rooms; and in small laboratories.

Key program features, including sterilization times, temperature, maximum load sizes, and recommended use of each program are listed in the following chart:

EZ Plus Series

Program	Recommended Use	Sterilization Temperature	Number of Dynamic Air Removal Pulses	Sterilization Time (minutes)	Dry Time
1	unwrapped instruments	132°C	EZ9 - 0 (gravity) EZ11 - 1 EZ15 - 1	3	1
2	wrapped instruments, pouches	132°C	EZ9 - 1 EZ11 - 2 EZ15 - 1	4	30
3	unwrapped delicate instruments	121°C	EZ9 - 0 (gravity) EZ11 - 1 EZ15 - 1	30	1
4	handpieces	132°C	EZ9 - 7 EZ11 - 7 EZ15 - 5	4	30

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Property	EZ9 Plus	EZ11 Plus	EZ15 Plus
Chamber diameter	230 mm (9")	280 mm (11")	380mm (15")
Chamber depth	504 mm (19.8")	504 mm (19.8")	760mm (30")
Chamber volume	19.8 ltr (5.2 gal)	28.5 ltr (7.5 gal)	84 ltr (22 gal)
Maximum load per tray	2.0 kg (4.4 lbs)	2.0 kg (4.4 lbs)	6 kg (11 lbs)
Maximum solid load	3.6 kg (8.0 lbs)	5.4 kg (12 lbs)	10 kg (22 lbs)
Number of trays	3	5	2

Technology:

The EZ Plus Series autoclaves are steam sterilizers composed of a pressure vessel that utilize electric heating elements to produce the sterilizing agent, steam. These autoclaves contain an electronic control system that makes the device automatic and fully-configurable.

Non-Clinical Testing:

Tuttnauer conducted validation studies in accordance with AAMI/ANSI ST55:2003. Testing shows that the EZ Plus Series autoclaves meet all aspects of the standard, including physical and microbiological performance requirements.

Since the EZ15 Plus autoclave is larger than provided under the table top standard of AAMI/ANSI ST55:2003, and since that standard therefore does not technically apply to the EZ15 Plus autoclave, Tuttnauer provides a summary of non-clinical testing performed for that model:

- Sterilization efficacy validation testing according to AAMI ST8. Handpiece testing was conducted to AAMI ST55, even though the model size technically removes the device from this standard. Sterility was validated to a sterility assurance level of 10^{-6} using the biological indicator overkill method. The testing consisted of a one-half cycle tests based on each of the 4 pre-programmed sterilization cycles. Testing with a fully loaded chamber. The test loads included instruments such as handpieces and lumen devices in the appropriate cycles.
- Thermal profile testing was conducted based on the AAMI ST8 guidelines. The testing was conducted using cycles based on the 4 pre-programmed sterilization cycles; however, in some cases, less air removal pulses were necessary to achieve the required sterilization temperature. Recorded temperature data demonstrated that the EZ15 Plus autoclave achieves the appropriate temperatures throughout the sterilization chamber, and that these

temperatures can be maintained in a steady state during the exposure phase of the sterilization cycles.

- Dry time testing was conducted based on the dry time tests outlined in AAMI ST8 and AAMI ST55 for wrapped cycles only (cycles 2 and 4). Testing included fabric wrapped instruments as well as paper/plastic pouch wrapped instruments. All results met or exceeded the minimum dry time criteria under the standards.

Conclusion:

The EZ9 Plus and EZ11 Plus autoclaves conform to all appropriate standards including the AAMI ST55 standard for table-top autoclaves. Additionally, as described in the summary comparison table, the characteristics of the autoclaves are substantially equivalent to the predicate devices in size, technology and operation. The EZ15 Plus also generally conforms to AAMI ST55 (except for chamber size) as well as AAMI ST8 for larger autoclaves. The testing to those standards is summarized above. The tests are appropriate for the EZ15 Plus based on intended use of the autoclave. The EZ15 Plus autoclave is also substantially equivalent in size, technology, and operation to the predicates summarized in the comparison table.

For all of the foregoing reasons, Tuttnauer believes that the EZ Plus Series autoclaves 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
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Tuttnauer Company, Limited
C/O Mr. Theodore Sullivan
Counsel
Buchanan Ingersoll & Rooney, P.C.
1700 K Street N.W., Suite 300
Washington, District of Columbia 20006

DEC - 8 2011

Re: K111736
Trade/Device Name: Tuttnauer EZ9 Plus Electronic Table-Top Autoclave; EZ11 Plus Electronic Table-Top Autoclave; and EZ15 Plus Electronic Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: November 23, 2011
Received: November 25, 2011

Dear Mr. Sullivan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K111736

Device Name: Tuttnauer EZ9 Plus Electronic Table-top Autoclave; EZ11 Plus Electronic Table-top Autoclave; and EZ15 Plus Electronic Autoclave

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Maximum solid	4.1 kg (9.0 lbs)	6.8 kg (15 lbs)	10 kg (22 lbs)

load			
Number of trays	3	5	2

Prescription Use ____ AND/OR Over-the-Counter Use _X_
(21 C.F.R. 801 Subpart D) (21 C.F.R. 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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