



January 15, 2015

Tuttnauer USA Co. Ltd.
C/O Mr. Theodore Sullivan
Official Correspondent
Buchanan, Ingersoll, & Rooney PC
1700 K Street NW
Washington, DC 20006

Re: K143311

Trade/Device Name: Tuttnauer Pre-Vacuum Tabletop Autoclave (Model ELARA-11); Tuttnauer Pre-Vacuum Horizontal Autoclave (Model 5075 HSG)

Regulation Number: 21 CFR 880.6880

Regulation Name: Steam Sterilizer

Regulatory Class: II

Product Code: FLE

Dated: November 18, 2014

Received: November 18, 2014

Dear Mr. Theodore 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K143311

Device Name: Tuttnauer ELARA-11 Pre-vacuum Tabletop Autoclave; Tuttnauer Pre-vacuum Horizontal Autoclave Model 5075 HSG

Indications for Use:

The ELARA-11 is a table-top autoclave 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, medical clinics; and in first aid rooms.

The ELARA-11 is validated for use in sterilizing lumened device of no longer than 230 mm and no smaller than 3.4 mm for sterilization programs 2 and 4.

The ELARA-11 is validated for use in sterilizing fabric packs/textiles for sterilization programs 2 and 4.

The ELARA-11 is validated for use in sterilizing up to six dental handpieces for sterilization programs 2 and 4.

The Model 5075 HSG is a horizontal autoclave designed for the sterilization of wrapped and unwrapped instruments and related items found in dental, medical and veterinary clinics, first aid rooms, and hospitals.

The Model 5075 is validated for use in sterilizing lumened device of no longer than 370 mm and no smaller than 3.8 mm for sterilization programs 2 and 3.

The Model 5075 is validated for use in fabric packs/textiles for sterilization programs 2 and 4.

Programs:

Key program features, including cycle times, temperature, dry times, and descriptions of each program for each device are listed in the following charts:

ELARA-11

Chamber Diameter 280 mm (11")
Chamber Depth 504 mm (19.8")
Chamber Volume 28.5 liters (7.5 gal)
Maximum load 8.0 kg (17.6 lbs)

<u>Program</u>	<u>Description</u>	<u>Sterilization Temperature</u> (°C/°F)	<u>Sterilization Time (minutes)</u>	<u>Dry Time (minutes)</u>
----------------	--------------------	---	-------------------------------------	---------------------------

1	Unwrapped instruments	134/273	4	1
2	Wrapped instruments	134/273	4	20
3	Unwrapped delicate instruments	121/250	20	1
4	Wrapped delicate instruments	121/250	20	20
Test 1	Bowie & Dick	134/273	3.5	2
Test 2	Vacuum Test	N/A	Test time 5+10	N/A

Sterilization programs 2 and 4 can be used for sterilizing lumened device of no longer than 230 mm and no smaller than 3.4 mm.

Sterilization programs 2 and 4 can be used in sterilizing fabric packs/textiles.

Sterilization programs 2 and 4 can be used in sterilizing up to six dental handpieces.

All sterilization programs utilize a pre-vacuum step

Model 5075 HSG

(Chamber Diameter 49.4 cm (26.0")
Chamber Depth 75.0 cm (29.5")
Chamber Volume 160 liters (42.3 gal)
Maximum Load 15 kg (33 lbs)

<u>Program</u>	<u>Description</u>	<u>Sterilization Temperature (°C/°F)</u>	<u>Sterilization Time (minutes)</u>	<u>Dry Time (minutes)</u>	<u>Max Load</u>
1	Unwrapped instruments	134/273	4	1	15kg
2	Wrapped instruments	134/273	4	20	15kg
3	Unwrapped delicate instruments	121/250	20	1	15kg
4	Wrapped delicate instruments	121/250	20	20	15kg
Test 1	Bowie & Dick	134/273	3.5	2	--
Test 2	Vacuum Test	N/A	Test time 5+10	N/A	--

Sterilization programs 2 and 3 can be used in sterilizing lumened device of no longer than 370 mm and no smaller than 3.8 mm.

Sterilization programs 2 and 4 can be used in sterilizing fabric packs/textiles.

All sterilization programs utilize a pre-vacuum step

Prescription Use _____
(21 C.F.R. 801 Subpart D)

AND/OR

Over-the-Counter Use X
(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)

510(k) Summary - K143311

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: January 5, 2015

Common Name: Electronic pre-vacuum autoclave, steam sterilizer

Trade Name: Tuttnauer Pre-Vacuum Tabletop Autoclave (Model ELARA-11); Tuttnauer Pre-Vacuum Horizontal Autoclave (Model 5075 HSG)

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

Substantial Equivalence:

The ELARA-11 and Model 5075 HSG are claimed to be substantially equivalent to the autoclaves cleared under K090783 and K063711. Like these autoclaves, the ELARA-11 and Model 5075 HSG contain an electronic control panel that permits automatic usage, and contains software equivalent to that in autoclaves cleared under K090783 and K063711. The ELARA-11 is a smaller model than the models cleared under K063711 (*i.e.*, it is designed for a countertop), but is nearly identical in size to the model previously cleared under K090783. The Model 5075 HSG is larger than the previously cleared models. The nominal parameters (*e.g.*, sterilization temperature and time; and dry time) are also different for the ELARA-11 and Model 5075 HSG than for the devices under K063711, but are identical to the parameters for the previously cleared ELARA-11 model (K090783). Further, all devices use steam as the sterilization agent.

The autoclaves are substantially equivalent to the Millennium B pre-vacuum autoclave cleared under K050263 based on general principles of operation as a steam sterilizer, and specifically for the device's electronic control, pre-vacuum operation, and post-vacuum drying stage.

The autoclaves substantially equivalent to the Tuttnauer EZ series autoclaves cleared under K111736. This is based on general principles of operation as a steam sterilizer, and specifically for the device's electronic control and software which are almost identical to those

found in the ELARA-11 and Model 5075 HSG (the only changes being those required due to mechanical differences and software version)..

Specific substantial equivalence to the predicate models is described in the comparison tables below.

Comparison Tables

Device Features	Tuttnauer ELARA-11 Pre/post Vacuum Tabletop Autoclave	K111736: Tuttnauer EZ Plus Series Electronic Tabletop Autoclaves -	K090783: Tuttnauer ELARA-11 Pre-vacuum Tabletop Autoclave	K063711: Tuttnauer Electronic Pre-vacuum Autoclaves	K050263: MOCOM Millennium B Series Autoclaves
Indications	The ELARA-11 is a tabletop autoclave designed for sterilization of medical and surgical goods, including both wrapped and unwrapped, solid, hollow, porous products and tubes in ophthalmic, dental, and medical clinics; and in first aid rooms.	The EZ Plus Series autoclaves are table-top autoclave 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 ELARA-11 is a table-top autoclave 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.	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.	The device is intended to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental hand-pieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.
Operating Principle/Sterilization Method	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent
Sterilization Cycle Types	pre-vacuum sterilizer w/ post-vacuum drying	Steam-flush pressure-pulse (Dynamic air removal); Gravity	Pre-vacuum; Gravity	Pre-vacuum; Gravity	pre-vacuum sterilizer w/ post-vacuum drying
General Sterilization Cycles	Unwrapped - 134C for 4 min. Wrapped - 134C for 4 min. Wrapped/Delicate instruments - 121C for 20 minutes Wrapped/Delicate instruments - 121C for 20 minutes and dry for 20 minutes All cycles are pre-vacuum sterilization cycles.	Unwrapped - 132C for 3 min. Wrapped - 132C for 4 min. Unwrapped delicate instruments - 121C for 30 min Handpieces - 132C for 4 minutes	Unwrapped - 134C for 4 min. Wrapped - 134C for 4 min. Wrapped/Delicate instruments - 121C for 20 minutes	Unwrapped - 132C Unwrapped - 121C Wrapped - 132C Wrapped - 134C Liquids - 121C	Porous – 134C for 4 minutes Porous – 121C for 20 minutes Hollow – 134C for 4 minutes Hollow – 121C for 20 minutes Wrapped – 134C for 4 minutes Wrapped – 121C for 20 minutes Solid – 134C for 4 minutes Solid – 134C for 20 minutes
Chamber Dimensions	11"(d) x 19.8"(l)	9"(d) x 19.8"(l) 11"(d) x 19.8"(l) 15"(d) x 30"(l)	11" (d) x 19.8"(l)	24" x 36" x 36" 26" x 26" x 50" 24" x 36" x 60" 24" x 36" x 48" 24" x 36" x 83" 26" x 26" x 39"	
Chamber/water path Materials	316 or 304 grade stainless steel	316 or 304 grade stainless steel	316 or 304 grade stainless steel	316 or 304 grade stainless steel	
Controls	Electronic/computer control	Electronic/computer control	Electronic/computer control	Electronic/computer control	Electronic/computer control

Device Features	Tuttnauer Model 5075 HSG Autoclave	K111736: Tuttnauer EZ Plus Series Electronic Tabletop Autoclaves -	K090783: Tuttnauer ELARA-11 Pre-vacuum Tabletop Autoclave	K063711: Tuttnauer Electronic Pre-vacuum Autoclaves	K050263: MOCOM Millennium B Series Autoclaves
Indications	The Model 5075 HSG-D is a autoclave designed for sterilization both wrapped and unwrapped instruments and related items found in dental, medical, and veterinary clinics, first aid rooms, and hospitals.	The EZ Plus Series autoclaves are table-top autoclave 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 ELARA-11" is a table-top autoclave 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.	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.	The device is intended to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental hand-pieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.
Operating Principle/Sterilization Method	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent	Sterilization using steam as the sterilizing agent
Sterilization Cycle Types	pre-vacuum sterilizer w/ post-vacuum drying	Steam-flush pressure-pulse (Dynamic air removal); Gravity	Pre-vacuum; Gravity	Pre-vacuum; Gravity	pre-vacuum sterilizer w/ post-vacuum drying
General Sterilization Cycles	Unwrapped - 134C for 4 min. Wrapped - 134C for 4 min. Wrapped/Delicate instruments - 121C for 20 minutes Wrapped/Delicate instruments - 121C for 20 minutes and dry for 20 minutes All cycles are pre-vacuum sterilization cycles.	Unwrapped - 132C for 3 min. Wrapped - 132C for 4 min. Unwrapped delicate instruments - 121C for 30 min Handpieces - 132C for 4 minutes	Unwrapped - 134C for 4 min. Wrapped - 134C for 4 min. Wrapped/Delicate instruments - 121C for 20 minutes	Unwrapped - 132C Unwrapped - 121C Wrapped - 132C Wrapped - 134C Liquids - 121C	Porous – 134C for 4 minutes Porous – 121C for 20 minutes Hollow – 134C for 4 minutes Hollow – 121C for 20 minutes Wrapped – 134C for 4 minutes Wrapped – 121C for 20 minutes Solid – 134C for 4 minutes Solid – 134C for 20 minutes
Chamber Dimensions	26"(d) x 29.5"(l)	9"(d) x 19.8"(l) 11"(d) x 19.8"(l) 15"(d) x 30"(l)	11" (d) x 19.8"(l)	24" x 36" x 36" 26" x 26" x 50" 24" x 36" x 60" 24" x 36" x 48" 24" x 36" x 83" 26" x 26" x 39"	
Chamber/water path Materials	316 or 304 grade stainless steel	316 or 304 grade stainless steel	316 or 304 grade stainless steel	316 or 304 grade stainless steel	
Controls	Electronic/computer control	Electronic/computer control	Electronic/computer control	Electronic/computer control	Electronic/computer control

General Description:

The ELARA-11 is a tabletop autoclave designed for sterilization of medical and surgical goods, including both wrapped and unwrapped, solid, hollow, porous products and tubes in ophthalmic, dental, and medical clinics; and in first aid rooms. The Model 5075 HSG is a horizontal autoclave designed for the sterilization of wrapped and unwrapped instruments and related items found in dental, medical and veterinary clinics, first aid rooms, and hospitals. These two devices are pre-vacuum and post-vacuum sterilizers that have an air removal stage (*i.e.*, pre-vacuum) before the start of the sterilization stage, as well as a post-sterilization drying stage that is based upon the combined operation of heat plus vacuum with air inlet pulses. The sterilizing agent is steam that is electrically-generated from either mineral-free or distilled water that is added to the built-in reservoir.

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 ELARA-11 is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. The device has several safety features, including a single manual safety door with a double-safety locking mechanism and an automatic safety shutoff. The front panel of the device consists of a display screen, a keypad, and a printer. The ELARA-11 electronic control system is automatic, fully-configurable, and has a total of six (6) programs: four (4) sterilization programs and two (2) test programs (Bowie & Dick test program with fixed (non-adjustable) parameters, and the Vacuum Test program). The components are made of varying grades of stainless steel.

The 5075 HSG model is a steam sterilizer composed of a pressure vessel, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. The device has several safety features, including a single manual safety door containing a double-safety locking mechanism, an automatic safety valve to protect personnel and equipment against build-up of high pressure, and a pressure gauge that indicates when there has been a failure in operation. The front panel of the device consists of a display screen, a keypad, and a printer. The 5075 HSG model electronic control system is automatic, fully-configurable, and has a total of six (6) programs: four (4) sterilization programs and two (2) test programs (Bowie & Dick test program with fixed (non-adjustable) parameters, and the Vacuum Test program). The components are made of varying grades of stainless steel and carbon steel.

Comparison to Cleared Devices:

Although the ELARA-11 and Model 5075 HSG, and the models cleared under K063711 and K090783 differ in device size and program cycles, they all operate with an electronic control panel that permits automated usage, and all models utilize the same operational software. Furthermore, they all use steam as the sterilization agent.

Intended Use:

The ELARA-11 is a table-top autoclave 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; and in first aid rooms.

The ELARA-11 is validated for use in sterilizing lumened device of no longer than 230 mm and no smaller than 3.4 mm for sterilization programs 2 and 4.

The ELARA-11 is validated for use in sterilizing fabric packs/textiles for sterilization programs 2 and 4.

The ELARA-11 is validated for use in sterilizing up to six dental handpieces for sterilization programs 2 and 4.

The Model 5075 HSG is a horizontal autoclave designed for the sterilization of wrapped and unwrapped instruments and related items found in dental, medical and veterinary clinics, first aid rooms, and hospitals.

The Model 5075 is validated for use in sterilizing lumened device of no longer than 370 mm and no smaller than 3.8 mm for sterilization programs 2 and 3.

The Model 5075 is validated for use in fabric packs/textiles for sterilization programs 2 and 4.

Technology:

The ELARA-11 is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. It contains an electronic control system that makes the device automatic and fully-configurable.

The Model 5075 HSG is a steam sterilizer composed of a pressure vessel, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. They contain an electronic control system that makes the device automatic and fully-configurable.

Non-Clinical and Performance Testing:

Tuttnauer conducted validation studies in accordance with AAMI/ANSI ST55:2003. Testing shows that the ELARA-11 and Model 5075 HSG meet all aspects of the standard, including physical and microbiological performance requirements. This testing included validation testing of all sterilization cycles using the biological indicator overkill method. The sterilizers meet all AAMI/ANSI testing requirements.

Conclusion:

. Based on the performance testing the subject device is substantially equivalent to the predicate devices.