December 16, 2022

Tuttnauer LTD.
Robert Basile
Senior Vice President
Har-Tuv Industrial Zone
Beit-Shemesh, Jerusalem 9910101
Israel

Re: K222608
Trade/Device Name: Tuttnauer Pre-vacuum Steam Sterilizer models 3870HSG and 3870HSG-WS
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: August 29, 2022
Received: August 29, 2022

Dear Robert Basile:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222608

Device Name
Tuttnauer Pre-vacuum Steam Sterilizer models 3870HSG and 3870HSG-WS

Indications for Use *(Describe)*
The pre-vacuum steam sterilizer models 3870HSG and 3870HSG-WS are intended for use in hospitals and other health-care facilities (e.g. hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices) for the purpose of sterilizing heat stable medical devices: wrapped and unwrapped solids (IUSS), hollow and porous products.

The following table show the preprogrammed cycles, including sterilization temperature, sterilization time (in minutes), dry time (in minutes) and maximum load:

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Table 1: standard cycles for model 3870HSG & 3870HSG-WS

Cycle name	Sterilization temperature [°C]	Sterilization Time [minute]	Dry Time [minute]	Maximum Load
IUSS	134	4	2	Tools – 12 kg (26.46 lbs.)
Wrapped	134	4	20	Textile – 2 packs
	134	4	20	Wrapped Tools – 12 kg (26.46 lbs.)
IUSS delicate	121	20	2	Tools – 12 kg (26.46 lbs.)
Wrapped delicate	121	20	20	Textile – 2 packs
	121	20	20	Wrapped Tools – 12 kg (26.46 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

K222608 510(k) Summary

1. SUBMITTER

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Date Prepared:
August 29, 2022

2. DEVICE

Trade Name: Tuttnauer Pre-vacuum Steam Sterilizer models 3870HSG and 3870HSG-WS

Common Name: Electronic Pre-vacuum Steam sterilizer (autoclave)

Classification:

Regulation description:	Steam sterilizer
Regulation medical specialty:	General hospital
Product code:	FLE
Regulation number:	880.6880
Device class:	II

3. PREDICATE DEVICES:

- Tuttnauer pre-vacuum horizontal autoclave model 5075HSG, which was cleared under K143311.

Product Code: FLE
Regulation Number: 21CFR 880.6880

4. DEVICE DESCRIPTION

The autoclave models 3870HSG-WS and the 3870HSG are dynamic-air-removal steam-heated sterilizers that are using steam as the sterilizing agent, which are suitable for large medical centers, dental clinics and operating rooms for the purpose of sterilizing heat stable medical devices: wrapped and unwrapped solids (IUSS), hollow and porous products.

The model 3870HSG-WS has an automatic door and is designed to be a fast cycle sterilizer that is mobile and can operate independent of building utilities due to its internal water reservoirs. The autoclave includes the option of water recycling, which allows the operator to manually fill the tap water reservoir with water that will be reused for 10 cycles, after which the reservoir is automatically drained and, in case the device is connected to a water inlet connection, be refilled automatically.

The model 3870HSG has an automatic door and is designed to be a fast cycle sterilizer. Contrary to the 3870HSG-WS, the 3870HSG need to be connected to the building utilities system (the water system). For both autoclave configurations (HSG/HSG-WS) a 9kW built-in steam generator is used to supply the steam for the sterilization process.

The autoclaves are Class B devices equipped with a vacuum system that allows:

- Removal of residual air from packs and porous load and most kinds of tubes (rubber, plastic etc.) by vacuum at the first stage of the cycle.
- Better steam penetration into the load; resulting in effective sterilization.
- Better temperature uniformity.
- Post sterilization drying phase - during the drying stage draws air through a HEPA filter (0.2µm) and pushes that air through the heated chamber to remove moisture and facilitate the drying operation. Drying is performed with the door closed.

The autoclave models 3870HSG-WS and 3870HSG are stand-alone devices that do not need to interact with other devices or to interact with any person(s) or patient(s) besides the current device operator.

The following tables show the properties for autoclave models 3870HSG-WS and 3870HSG:

Table 1: properties of model 3870HSG-WS and 3870HSG

Property		**Values**
Chamber	Diam.	~15" (38cm)
	Depth	~27" (68.5cm)
Chamber volume		3ft^3 (85liters)
Max. Allowable Working pressure (MAWP)		~40.6psi (2.8bar)
Net weight		~701lbs (318kg)
Shipping weight		~750lbs (340kg)
Floor loading requirements		According to the Overall weight and floor requirements
Max load		Fabric – 2 packs Instruments – ~26.5 lbs. (12 kg)
Tray dimensions	Big	~14" x ~26" x ~1" (35 x 67 x 2.5 cm)
	Small	~11" x ~26" x ~1" (28 x 67 x 2.5 cm)
No. of trays		2
Load No. counter		Counting from 0 to 999 and nullifies.

Both autoclaves offer a choice of automatic programs designed to match the material to be sterilized. The programs included in the device are:

- Programs for Un-wrapped Loads
- Programs for Wrapped Loads.
- Two Test Programs: The Bowie & Dick Test and the Vacuum Test

A computerized control unit ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and printing of sterilization data. The selected program, the main phases of the cycle and the status of the machine are displayed on digital display. The device can display the pressure in psia, psig, or in kPa according to the operator's requirements. The operation of the autoclave is done via integrated keypad located below the screen.

For process documentation, the information concerning the cycles is printed from an integrated printer. By using the Remote PC Reporting application (R.PC.R) it is possible to generate Data and Trends reports on cycle data from the cycle data downloaded from the

autoclave. Both models feature a built-in memory to record up to 100 sterilization cycles. These can be reprinted on the printer or exported to a USB device to be transferred to a PC (using the R.PC.R application).

5. LIST OF DEVICES

The following table is a list of devices models for which this 510(k) clearance is requested in this submission:

Table 2: List of devices models in the current submission

Device model	Device catalog no.	Device description
3870HSG-WS	3870HSG-WS-230-D	An autoclave with a chamber volume of 85L, operating in 3Ph 230V 50/60Hz with a generator of 9kW The autoclave is a stand-alone device with an internal water recycle system to allow several runs before replacing/filling the water
3870HSG	3870HSG-230-D	An autoclave with a chamber volume of 85L, operating in 3Ph 230V 50/60Hz with a generator of 9kW The autoclave is a stand-alone device that needs to be connected to the site's water system to operate.

6. INDICATION FOR USE

The pre-vacuum steam sterilizer models 3870HSG-WS and 3870HSG are intended for use in hospitals and other health-care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices) for the purpose of sterilizing heat stable medical devices: wrapped and unwrapped solids (IUSS), hollow and porous products.

The following table show the preprogrammed cycles for each of the mentioned models, including sterilization temperature, sterilization time (in minutes), dry time (in minutes) and maximum load:

Table 3: standard cycles for models 3870HSG-WS and 3870HSG

Cycle name	Sterilization temperature [°C]	Sterilization Time [minute]	Dry Time [minute]	Maximum Load
IUSS	134	4	2	Tools – 12 kg (26.46 lbs.)
Wrapped	134	4	20	Textile – 2 packs
	134	4	20	Wrapped Tools – 12 kg (26.46 lbs.)
IUSS delicate*	121	20	2	Tools – 12 kg (26.46 lbs.)
Wrapped delicate	121	20	20	Textile – 4 packs
	121	20	20	Wrapped Tools – 12 kg (26.46 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Intended user

The autoclave models 3870HSG-WS and 3870HSG are intended for use by hospital personnel and other medical personnel.

All autoclave users must receive training in proper usage from an experienced employee. Every new employee must undergo a training period under an experienced employee.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following technological characteristics will be compared between the subject horizontal autoclave models 3870HSG-WS and 3870HSG and the cleared predicate horizontal autoclave model 5075HSG under K143311:

- Indication for use
- General design of device: chamber volume, dimensions, door mechanism;
- Materials;
- Energy source;
- Performance: operation principle, sterilization cycle type, sterilization time, controls;
- Utilities
- Sterilization parameters
- Maximum load

Reason for the 510(k):

Submission of a new device that is not marketed in the US.

Table 4: Comparison of technological characteristics with predicate device

Parameter	3870HSG	3870HSG-WS	5075HSG – under K143311	Comparison
Indication for use	The pre-vacuum steam sterilizer models 3870HSG and 3870HSG-WS are intended for use in hospitals and other health-care facilities (e.g. hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices) for the purpose of sterilizing heat stable medical devices: wrapped and unwrapped solids (IUSS), hollow and porous products.	The pre-vacuum steam sterilizer models 3870HSG and 3870HSG-WS are intended for use in hospitals and other health-care facilities (e.g. hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices) for the purpose of sterilizing heat stable medical devices: wrapped and unwrapped solids (IUSS), hollow and porous products.	The model 5075 is a horizontal autoclave designed for sterilization of wrapped and unwrapped instruments and related items found in dental, medical and veterinary clinics, first aid rooms and hospitals.	Different
Chamber dimensions	~15” (38cm) ID X ~27” (68.5cm) length	~15” (38cm) ID X ~27” (68.5cm) length	~26” (49.4cm) ID X ~29.5” (75cm) length	Different
Chamber volume	$3ft^3$ (85liters)	$3ft^3$ (85liters)	$5.65ft^3$ (160liters)	Different
Operating Principle / sterilization method	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Same
Sterilization cycle types	Pre & post vacuum	Pre & post vacuum	Pre & post vacuum	Same

Parameter	3870HSG	3870HSG-WS	5075HSG – under K143311	Comparison
Chamber Materials/water path materials	316 or 304 grade stainless steal	316 or 304 grade stainless steal	316 or 304 grade stainless steal	Same
Energy source	The device can be operated only while connected to an electrical source (the electrical grid). It has no internal power source (batteries).	The device can be operated only while connected to an electrical source (the electrical grid). It has no internal power source (batteries).	The device can be operated only while connected to an electrical source (the electrical grid). It has no internal power source (batteries).	Same
Controls	Electronic computer control	Electronic computer control	Electronic computer control	Same
Door mechanism	Automatic door	Automatic door	Manual door	Different
Water utilities	The device needs to be connected to the building water utilities.	The device has internal water reservoirs that allow it to be mobile and independent of water utilities	The device needs to be connected to the building water utilities.	Same for the 3870HSG model Different for the 3870HSG-WS model.
Maximum load	• Tools (solids) – 12kg (26.46lbs.) • Textile – 2 packs	• Tools (solids) – 12kg (26.46lbs.) • Textile – 2 packs	• Tools (solids) – 15kg (33.07lbs.) • Textile – 14kg (30.86lbs.)	Different
Cycle parameters	• IUSS – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 2min. • Wrapped – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp.	• IUSS – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 1min. • Wrapped – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp.	• Unwrapped instruments – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 1min. • Wrapped – sterilization temp. of 134ºC / 273ºF for 4min, dry time of 20min.	Different

Parameter	3870HSG	3870HSG-WS	5075HSG – under K143311	Comparison
	of 121ºC / 250ºF for 20min, dry time for 2min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 20min, dry time of 20min.	of 121ºC / 250ºF for 20min, dry time for 1min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 20min, dry time of 20min.	• Unwrapped delicate instruments – sterilization temp. of 121ºC / 250ºF for 20min, dry time for 1min. Wrapped delicate – sterilization temp of 121ºC / 250ºF for 20min, dry time of 20min.	

8. PERFORMANCE TESTING

The following shows the non-clinical tests conducted:

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
Electrical Safety	Verifying that device and its components meet electrical safety requirements	Meeting standard specification	• IEC 61010-1:2010 /UL 61010-1:2012 • IEC 61010-2-040:2015	Pass
EMC	Verifying that the device meets EMC requirements	Meeting standard specification	• EN 61326-1:2013 / IEC 61326-1:2012	Pass
Pressure vessel testing	Verifying that the pressure vessel used for the T-Edge meets the requirements for pressure vessel and is safe for use.	Meeting standard specification	• ASME Boiler and pressure vessel code, Section VIII division 1	Pass
Device performance tests				
Bowie & Dick test	Verify air removal performance (for	The Bowie-Dick test indicator sheet shall	• ANSI/AAMI ST-8	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
	dynamic air removal sterilizers)	show a uniform color change		
Air-leak-rate (vacuum) test	Verify air removal performance (for dynamic air removal sterilizers)	average leak rate of 1 millimeter of mercury (mmHg) (0.13 kPa) (0.019 psia) per min or less over the measured time interval.	• ANSI/AAMI ST-8	Pass
Empty chamber tests (121℃/132℃) – on wrapped and unwrapped (IUSS) load	to ensure that the sterilizer is capable of providing steady-state thermal conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load	The temperature shall not exceed more than 3°C above the sterilization temperature. The temperature shall not be below the sterilization temperature Actual exposure time	• ANSI/AAMI ST-8	Pass
Full chamber load test (121℃/132℃) – on wrapped and unwrapped (IUSS) load	to ensure that the sterilizer is capable of providing steady-state thermal conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load	The temperature shall not exceed more than 3°C above the sterilization temperature. The temperature shall not be below the sterilization temperature Actual exposure time	• ANSI/AAMI ST-8	Pass
Moisture retention tests – fabric PCD and wrapped instruments PCD	to ensure that the sterilizer is capable of meeting the moisture retention criteria	Moisture retained by the fabric PCD shall cause no more than a 3% increase in pre-sterilization test pack weight, and the pack	• ANSI/AAMI ST-8	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
		shall exhibit no wet spots. When examined immediately after completion of the cycle, the wrapped instrument packs shall have no wet spots on the outer wrappers. Moisture retained by the 100% cotton towel shall cause no more than a 20% increase in the pre-sterilization weight of the towel.		
Biological performance with a textile PCD	Verifying biological performance on half sterilization time	Tested cycle has a 10^{-6} SAL or an SAL providing a greater assurance of sterility when the textile PCD is used.	• ANSI/AAMI ST-8	Pass
Biological performance with wrapped instrument PCD	Verifying biological performance on half sterilization time	Tested cycle has a 10^{-6} SAL or an SAL providing a greater assurance of sterility when the wrapped instrument PCD is used.	• ANSI/AAMI ST-8	Pass
Biological performance with unwrapped instrument PCD (IUSS) – minimum and maximum load tests	Verifying biological performance on half sterilization time	There shall be no growth observed in the vials containing turbines or in the extraction of any of the turbines, except for the positive controls. No growth shall be observed with the BIs except the positive control BI. Growth should	• ANSI/AAMI ST-8	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
		be observed for the positive control turbine and BI.		

9. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the autoclaves models 3870HSG and 3870HSG-WS, are as safe, as effective, and performs as well as or better than the legally marketed device cleared under K143311.