September 20, 2022

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

Re: K221227
Trade/Device Name: Tuttnauer Horizontal autoclave series model: 4472, 5596, 6690, 66120
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: August 22, 2022
Received: August 22, 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,

Clarence W. Murray, III, PhD
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)*
K221227

Device Name
Tuttnauer Horizontal autoclave models: 4472, 5596, 6690 and 66120

Indications for Use *(Describe)*
The Tuttnauer Horizontal autoclave models 4472, 5596, 6690 and 66120 are intended for use by health care providers to sterilize medical products by means of pressurized steam. The devices are autoclaves that are intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.

The following tables show the validated cycles, including sterilization temperature, sterilization time (in minutes), dry time (in minutes) and maximum load for tools (in kilograms) and textile (in packs) for each of the models mentioned:

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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Sterilization Programs for submitted models

Table 1: standard cycles for model 4472

Model 4472 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS	132	3	2	Tools – 23 kg (50.7 lbs.)
Wrapped	132	4	20	Textile – 4 packs
	132	4	20	Wrapped Tools – 23 kg (50.7 lbs.)
IUSS delicate	121	30	2	Tools – 23 kg (50.7 lbs.)
Wrapped delicate	121	30	20	Textile – 4 packs
	121	30	20	Wrapped Tools – 23 kg (50.7 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Table 2: standard cycles for model 5596

Model 5596 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS	132	3	2	Tools – 34 kg (75 lbs.)
Wrapped	132	4	20	Textile – 6 packs
	132	4	20	Wrapped Tools – 34 kg (75 lbs.)
IUSS delicate	121	30	2	Tools – 34 kg (75 lbs.)
Wrapped delicate	121	30	20	Textile – 6 packs
	121	30	20	Wrapped Tools – 34 kg (75 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Table 3: standard cycles for model 6690

Model 6690 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS	132	3	2	Tools – 102.1 kg (225 lbs.)
Wrapped	132	4	20	Textile – 12 packs
	132	4	20	Wrapped Tools – 102.1 kg (225 lbs.)
IUSS delicate	121	30	2	Tools – 102.1 kg
Wrapped delicate	121	30	20	Textile – 12 Packs
	121	30	20	Wrapped Tools – 102.1 kg (225 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Table 4: standard cycles for model 66120

Model 66120 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS	132	3	2	Tools – 136 kg (300 lbs.)
Wrapped	132	4	20	Textile – 16 packs
	132	4	20	Wrapped Tools – 136 kg (300 lbs.)
IUSS delicate	121	30	2	Tools – 136 kg (300 lbs.)
Wrapped delicate	121	30	20	Textile – 16 packs
	121	30	20	Wrapped Tools – 136 kg (300 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

510k Summary

Submission: K221227
Device Models: 4472, 5596, 6690, 66120

Date Prepared: September 19, 2022

1. SUBMITTER

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2. DEVICE

Trade Name: Tuttnauer Horizontal autoclave series model: 4472, 5596, 6690 and 66120
Common Name: Horizontal Steam Sterilizer
Classification:

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

3. PREDICATE DEVICE

Primary Predicate: Tuttnauer 4472, 5596, 6690 and 66120 Horizontal Autoclave Models

Predicate Name	Product Code	Regulation Number	Regulation Name	Class	510k No.
4472, 5596, 6690 and 66120 Horizontal Autoclave	FLE	21CFR880.6880	Steam Sterilizer	II	K181456

4. DEVICE DESCRIPTION

The Tuttnauer horizontal autoclave series models 4472, 5596 and 6690 are dynamic-air-removal autoclaves that are designed for sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products. The sterilization medium is steam, which is directly introduced into the sterilization chamber. This eliminates the need to wait for water introduced into the chamber to boil and reach sterilization parameters. The autoclave operates in a temperature range of up to 137 C (279ºF) and pressure up to 2.3 bar (34psi).

Each of the mentioned models differ from each other in chamber size and include different 1 or 2 door configurations. The models can come with onboard steam generation capability, but other configurations are used with external steam sources.

The various configurations are provided as follows:

A. Door configurations:

Door configuration can be manual or automatic hinged or sliding, one door or two doors:

	Number of doors in the autoclave	
Door type	**1 door**	**2 doors**
Vertical sliding	1V	2V
Horizontal sliding	1H	2H
Manual hinged	1R	2R
Automatic hinged	1A	2A

The **vertical sliding** door is operated by two hydro-pneumatic cylinders, mounted laterally on both sides of the door. Each cylinder contains an integrated and separated oil system. The operation of the cylinders is performed by an air pressure and the oil system acts as a speed control system. An adjustable restrictor controls the flow of oil from one side to the other side on each cylinder, controlling the speed movement of the door.

The **horizontal sliding** door is operated by a hydro-pneumatic cylinder mounted above the door that is adjusted to operate in either the opening or closing direction. The cylinder contains an integrated and separated oil system. The operation of the cylinder is performed by air pressure and the oil system acts as a speed control system. An adjustable restrictor on the cylinder controls the flow of oil from one side to the other, controlling the speed movement of the door.

The **manual hinged** door is locked by rotating a wheel located on the front of the door. The closing mechanism incorporates a safety lock which locks the door in the closed position, preventing the door mechanism from opening. The door will only open if conditions in the chamber allow the locking mechanism to open the door.

The **automatic hinged** door is closed manually and is locked by an automatic pneumatic mechanism. Similarly, at the end of a cycle, the door is unlocked and can be opened manually.

The interlock system of the door is based on the following opening conditions:

- The door cannot be opened while the autoclave is in operation.
- The door cannot be opened if the chamber is under pressure.
- The door cannot be opened if there is liquid in the chamber.
- The door cannot be opened at the end of the cycle if the chamber temperature is higher than the pre-set final temperature.

B. Steam generation configuration:

  - EP – Electric Power – onboard steam generator
  - SP – Steam comes from External source
  - STS – Steam to Steam option, a unit supplied with the configuration that cleans the external industrial steam.

The horizontal autoclave models 4472, 5596, 6690 and 66120 include main components: a pressure vessel with steam jacket, a vacuum pump, a water pump and generator, depending on the configuration of the device. The vacuum pump can be replaced by an ejector, which is installed as part of the piping of the device and operates in a similar way to create vacuum.

An emergency stop-push button that is mounted on the front panel is an available option for customers with specific needs. This feature is designed to prevent hazards to humans, and accidents due to equipment breakdown. When the emergency switch is activated, the key must be used to allow the switch to return to the operating position.

The autoclave has an automatic shutdown system. If there are no operations for four hours, the autoclave goes into SLEEP mode.

The selected program, the main phases of the cycle and the status of the machine are controlled and displayed on digital readouts. For process documentation, the important information concerning operation is printed.

The Remote PC Reporting application, (R.PC.R), is used to generate Data and Trends reports on cycle data.

The electronic circuitry and software programming of the programmable control system are designed to operate:

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

The control system of the sterilizer is based on microcomputer technology. The computerized control unit ensures a fully automatic operation through the entire cycle. For all models mentioned, the software and controller are the same.

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 1: List of devices models in the current submission

Device model	Device catalog no.	Device description
4472	4472-1V 4472-2V 4472-1R 4472-2R 4472-1V-L-USA 4472-1V-R-USA	An autoclave with a chamber volume of 120L, operating in 1Ph 115V/60Hz or 3Ph 220V/60Hz depending on the configuration (see device manual). This device can come with: • one or two vertical sliding doors (1V or 2V) configuration, or • one or two manual hinged doors configuration (1R or 2R). With the piping to the left or right side of the device and, Several steam generation options: • EP – Electric Power – onboard steam generator • SP – Steam comes from external source • STS – Steam to Steam option, a unit supplied with the configuration that cleans the external industrial steam.

Device model	Device catalog no.	Device description
5596	5596-1V 5596-2V 5596-1R 5596-2R 5596-2V-USA 5596-1V-L-USA 5596-1V-R-USA 5596-1R-L-USA 5596-1R-R-USA	An autoclave with a chamber volume of 250L, operating in 1Ph 115V/60Hz or 3Ph 400V/60Hz depending on the configuration (see device manual). This device can come with: • one or two vertical sliding doors (1V or 2V) configuration, or • one or two manual hinged doors (1R or 2R) configuration With the piping to the left or right side of the device and, Several steam generation options: • EP – Electric Power – onboard steam generator • SP – Steam comes from external source • STS – Steam to Steam option, a unit supplied with the configuration that cleans the external industrial steam.
6690	6690-1A 6690-2A 6690LM-1V-USA 6690LM-2V-USA	An autoclave with a chamber volume of 430L, operating in 1Ph 115V/60Hz or 3Ph 208V/60Hz or 3Ph 400V/60Hz depending on the configuration (see device manual). This device can come with: • one or two vertical sliding doors (1V or 2V) configuration, or • one or two doors automatic hinged doors (1A or 2A) configuration. With the piping to the left or right side of the device and, Several steam generation options: • EP – Electric Power – onboard steam generator • SP – Steam comes from external source • STS – Steam to Steam option, a unit supplied with the configuration that cleans the external industrial steam.
66120	66120-1V 66120-2V	An autoclave with a chamber volume 530L, operating in 1Ph 115V/60Hz or 1Ph 120V/60Hz depending on the configuration (see device manual). This device can come with: • one or two vertical sliding doors (1V or 2V) configuration With the piping to the left or right side of the device and, Several steam generation options: • EP – Electric Power – onboard steam generator • SP – Steam comes from external source • STS – Steam to Steam option, a unit supplied with the configuration that cleans the external industrial steam.

6. INDICATION FOR USE

The Tuttnauer horizontal autoclave models 4472, 5596, 6690 and 66120 are intended for use by health care providers to sterilize medical products by means of pressurized steam. The devices are autoclaves that are intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.

The following tables show the preprogramed standard cycles for each of the mentioned models, including sterilization temperature, sterilization time (in minutes), dry time (in minutes) and maximum load for tools (in kilograms) and textile (in packs) for each of the models mentioned:

Table 2: standard cycles for model 4472

Model 4472 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS*	132	3	2	Tools – 23 kg (50.7 lbs.)
Wrapped	132	4	20	Textile – 4 packs
	132	4	20	Wrapped Tools – 23 kg (50.7 lbs.)
IUSS delicate*	121	30	2	Tools – 23 kg (50.7 lbs.)
Wrapped delicate	121	30	20	Textile – 4 packs
	121	30	20	Wrapped Tools – 23 kg (50.7 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Notes:
** IUSS – means immediate use steam sterilization*

Table 3: standard cycles for model 5596

Model 5596 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS*	132	3	2	Tools – 34 kg (75 lbs.)
Wrapped	132	4	20	Textile – 6 packs
	132	4	20	Wrapped Tools – 34 kg (75 lbs.)
IUSS delicate*	121	30	2	Tools – 34 kg (75 lbs.)
Wrapped delicate	121	30	20	Textile – 6 packs
	121	30	20	Wrapped Tools – 34 kg (75 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Notes:
** IUSS – means immediate use steam sterilization*

Table 4: standard cycles for model 6690

Model 6690 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS*	132	3	2	Tools – 102.1 kg (225 lbs.)
Wrapped	132	4	20	Textile – 12 packs
	132	4	20	Wrapped Tools – 102.1 kg (225 lbs.)
IUSS delicate*	121	30	2	Tools – 102.1 kg (225 lbs.)
Wrapped delicate	121	30	20	Textile – 12 Packs
	121	30	20	Wrapped Tools – 102.1 kg (225 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Notes:
** IUSS – means immediate use steam sterilization*

Table 5: standard cycles for model 66120

Model 6690 - All door configurations				
Cycle name	**Sterilization temperature [°C]**	**Sterilization Time [minute]**	**Dry Time [minute]**	**Maximum Load**
IUSS*	132	3	2	Tools – 136 kg (300 lbs.)
Wrapped	132	4	20	Textile – 16 packs
	132	4	20	Wrapped Tools – 136 kg (300 lbs.)
IUSS delicate*	121	30	2	Tools – 136 kg (300 lbs.)
Wrapped delicate	121	30	20	Textile – 16 Packs
	121	30	20	Wrapped Tools – 136 kg (300 lbs.)
Bowie and Dick	134	3.5	2	N/A
Vacuum test	N/A	N/A	N/A	N/A

Notes:
** IUSS – means immediate use steam sterilization*

Intended user

The horizontal autoclave models 4472, 5596, 6690 and 66120 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 4472, 5596, 6690 and 66120 and the cleared predicate horizontal autoclave models 4472, 5596, 6690 and 66120 under K181456:

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

Reason for the 510(k):

Increasement of the maximum load that can be sterilized in the Wrapped tools and Unwrapped tools (IUSS) cycles, and replacing the definition of the allowable maximum load in the Textile cycles from kilograms to number of packs for the horizontal autoclave models 4472, 5596, 6690 and 66120.

Table 6: model 4472 – Comparison of technological characteristics with predicate device

Parameter	4472 – K221227	4472 – under K181456	Comparison
Indication for use	The horizontal autoclave model 4472 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.	The horizontal autoclave model 4472 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped solids, hollow and porous products.	Different

Parameter	4472 – K221227	4472 – under K181456	Comparison
Chamber dimensions	16" x 16" x 29"	16" x 16" x 29"	Same
Chamber volume	4.24 ft^3 (120 L)	4.24 ft^3 (120 L)	Same
Operating Principle / sterilization method	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Same
Sterilization cycle types	Pre & post vacuum	Pre & post vacuum	Same
Vacuum system	Vacuum pump or ejector	Vacuum pump	Different
Chamber Materials	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).	Same
Controls	Electronic computer control	Electronic computer control	Same
Maximum Load	• Tools (solids) – 23 kg (50.7 lbs.) • Textile – 4 packs	• Tools (solids) – 23 kg (50.7 lbs.) • Textile – 11.1 kg	Different
Cycle parameters	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 2min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 2min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 1min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 1min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	Different

Table 7: model 5596 – Comparison of technological characteristics with predicate device

Parameter	5596 – K221227	5596 – under K181456	Comparison
Indication for use	The horizontal autoclave model 5596 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.	The horizontal autoclave model 5596 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped solids, hollow and porous products.	Different
Chamber dimensions	20" x 20" x 38"	20" x 20" x 38"	Same
Chamber volume	8.83 ft^3 (250 L)	8.83 ft^3 (250 L)	Same
Operating Principle / sterilization method	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Same
Sterilization cycle types	Pre & post vacuum	Pre & post vacuum	Same
Vacuum system	Vacuum pump or ejector	Vacuum pump	Different
Chamber Materials	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).	Same
Controls	Electronic computer control	Electronic computer control	Same
Maximum load	• Tools (solids) - 34 kg (75 lbs.) • Textile – 6 packs	• Tools (solids) – 23 kg (50.7 lbs.) • Textile – 22.2 kg	Different

Parameter	5596 – K221227	5596 – under K181456	Comparison
Cycle parameters	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 2min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 2min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 1min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 1min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	Different

Table 8: model 6690 – Comparison of technological characteristics with predicate device

Parameter	6690 – K221227	6690 – under K181456	Comparison
Indication for use	The horizontal autoclave model 6690 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.	The horizontal autoclave model 6690 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped solids, hollow and porous products.	Different
Chamber dimensions	26” x 26” x 39”	26” x 26” x 39”	Same
Chamber volume	15.19 ft^3 (430 L)	15.19 ft^3 (430 L)	Same

Parameter	6690 – K221227	6690 – under K181456	Comparison
Operating Principle / sterilization method	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Same
Sterilization cycle types	Pre & post vacuum	Pre & post vacuum	Same
Vacuum system	Vacuum pump or ejector	Vacuum pump	Different
Chamber Materials	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).	Same
Controls	Electronic computer control, not programmable	Electronic computer control, not programmable	Same
Maximum load	• Tools (solids) – 102.1 kg (225 lbs.) • Textile – 12 packs	• Tools (solids) - 46 kg (101.4 lbs.) • Textile – 33.3 kg	Different
Cycle parameters	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 2min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 2min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 1min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 1min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	Different

Table 9: model 66120 – Comparison of technological characteristics with predicate device

Parameter	66120 – K221227	66120 – under K181456	Comparison
Indication for use	The horizontal autoclave model 66120 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped and unwrapped (IUSS) solids, hollow and porous products.	The horizontal autoclave model 66120 is intended for use by health care providers to sterilize medical products by means of pressurized steam. The device is an autoclave that is intended to provide sterilization of heat stable medical devices: wrapped solids, hollow and porous products.	Different
Chamber dimensions	26" x 26" x 49"	26" x 26" x 49"	Same
Chamber volume	18.72 ft^3 (530 L)	18.72 ft^3 (530 L)	Same
Operating Principle / sterilization method	Sterilization using steam as sterilizing agent	Sterilization using steam as sterilizing agent	Same
Sterilization cycle types	Pre & post vacuum	Pre & post vacuum	Same
Vacuum system	Vacuum pump or ejector	Vacuum pump	Different
Chamber Materials	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).	Same
Controls	Electronic computer control, not programmable	Electronic computer control, not programmable	Same
Maximum load	• Tools (solids) – 136 kg (300 lbs.) • Textile – 16 packs	• Tools (solids) - 46 kg (101.4 lbs.) • Textile – 33.3 kg	Different

Parameter	66120 – K221227	66120 – under K181456	Comparison
Cycle parameters	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 2min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 2min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	• IUSS – sterilization temp. of 132ºC / 270ºF for 3min, dry time of 1min. • Wrapped – sterilization temp. of 132ºC / 270ºF for 4min, dry time of 20min. • IUSS delicate – sterilization temp. of 121ºC / 250ºF for 30min, dry time for 1min. • Wrapped delicate – sterilization temp of 121ºC / 250ºF for 30min, dry time of 20min.	Different

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 4472, 5596, 6690 and 66120 sterilizers meet the requirements for pressure vessel and is safe for use.	Meeting standard specification	• ASME Boiler and pressure vessel code, Section VIII division 1	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
Device performance tests				
Bowie & Dick test	Verify air removal performance (for dynamic air removal sterilizers)	The Bowie-Dick test indicator sheet shall show a uniform color change	• ANSI/AAMI ST-8	Pass
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

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No 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 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.	• ANSI/AAMI ST-8	Pass
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	
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	
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.	• ANSI/AAMI ST-8	

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
		No growth shall be observed with the BIs except the positive control BI. Growth should be observed for the positive control turbine and BI		

9. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the horizontal autoclaves models 4472, 5596, 6690 and 66120, are as safe, as effective, and performs as well as or better than the legally marketed device cleared under K181456.