November 27, 2023

Tuttnauer U.S.A Co, Ltd
Jonathan Lane
Global QA RA Manager
25 Power Drive Hauppauge
New York, New York 11788

Re: K232658
Trade/Device Name: T-Top (T-Top 10); T-Top (T-Top 11)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: August 4, 2023
Received: August 31, 2023

Dear Jonathan Lane:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Christopher K. Dugard, M.S.
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)*
K232658

Device Name
T-Top 10 & T-Top 11

Indications for Use *(Describe)*
The T-Top 10 & T-Top 11 tabletop autoclaves are designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical & dental offices).

The T-Top 10 and T-Top 11 devices are validated for use in:
• Unwrapped instruments, wrapped instruments and dental handpieces (Class S cycles).
• Unwrapped instruments, wrapped instruments, sterilizing dental handpieces and textiles/porous loads (Class B cycles).

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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Date Prepared: August 01, 2023

1. SUBMITTER

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2. DEVICE

Trade Name: T-Top 10 & T-Top 11
Common Name: Electronic autoclave
Classification Name: Steam Sterilizer
Classification:

Product Code	FLE
Regulatory Class:	II
Regulation Number:	21CFR 880.6880
Regulation Name:	Steam Sterilizer

3. PREDICATE DEVICES

Primary predicate: T-Edge 10 & T-Edge 11 autoclave

Predicate name	Product Code	Regulation Number	Regulation Name	Class	510K no.
T-Edge 10 & T-Edge 11	FLE	21CFR 880.6880	Steam Sterilizer	Class II	K213080

4. DEVICE DESCRIPTION

The autoclave is fully automatic (a computerized control unit ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and a clear documentation of the sterilization cycle. Drying is performed with the door closed).

This autoclave uses steam as a sterilizing agent.

The steam is produced by warming up a controlled amount of water inserted to a pipe heating element, and then to the chamber. This technique saves energy and water consumption.

The autoclave is equipped with a Pipe heating element and with chamber heaters to maintain the steam inside the chamber.

The autoclave is equipped with a vacuum system, which supports and improves:

- 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.
- Steam penetration into the load; resulting in effective sterilization.
- Temperature uniformity.
- Post sterilization drying phase

A touchscreen is used for monitoring and control purposes.

The device has 2 built -in USB ports to enable the operation of an external optional barcode printer:

- The barcode printer can print labels with a unique cycle ID barcode, operator name, sterilization and expiry dates
- One barcode printer can be connected to the machine.
- The printer connection to the machine, by using a USB socket, with a dedicated cable
- Barcode printer power supply voltage can range between 100-240V (external power supply - not from the USB socket).
- A barcode printer is an optional addition to the autoclave

The device features built-in memory to record up to 500 sterilization cycles. These can be exported to a USB device to be transferred to a PC.

The following tables show the cycles that were validated for Class-B and Class-S, including sterilization temperature, sterilization time in minutes and dry time in minutes:

Table 1: Class B key cycles

#	Cycle Name	Sterilization temperature [°F/°C]	Sterilization time [min]	Dry Time [min]		Max load 10" [Kg]	Max load 11" [Kg]
				10''	11''		
1	Unwrapped instruments 273F	273.2°F (134°C)	4	2	2	6	9
2	Wrapped Pouches 273F	273.2°F (134°C)	4	22	26	Instruments – 3.6	Instruments – 5.4
						Textile – 1.5	Textile – 2
						Handpieces – 5 units	
3	Wrapped Pouches 273F / 2kg	273.2°F (134°C)	4	15	15	Instruments – 1.8	Instruments – 2.7
						Textile – 0.75	Textile – 1
						Handpieces – 3 units	
4	Unwrapped Delicate 250F	249.8°F (121°C)	20	2	2	6	9
5	Wrapped Delicate 250F	249.8°F (121°C)	20	25	30	Instruments – 3.6	Instruments – 5.4
						Textile – 1.5	Textile – 2
6	B&D Test	273.2°F (134°C)	3.5	2		-	-
7	Vacuum Test	NA	NA	NA		-	-
8	System Clean	NA	NA	NA		-	-

*Wrapped pouches 273F partial load will not be tested because this is the same program as Wrapped pouches 273F, except for a different drying time. Wrapped pouches 273F was tested at full load and this is the worst case. Therefore, in this cycle, only dryness will be tested.

Table 2: Class S key cycles

#	Cycle Name	Sterilization temperature [°F/°C]	Sterilization time [min]	Dry Time [min]		Max load 10" [Kg]	Max load 11" [Kg]
				10''	11''		
1	Unwrapped instruments 270F	269.6°F (132°C)	4	2	2	5	8
2	Wrapped Pouches 270F	269.6°F (132°C)	4	25	26	3.6	4.5
3	Wrapped Pouches 270F / 2kg	269.6°F (132°C)	4	15	15	1.8	2.3
4	Unwrapped Delicate 250F	249.8°F (121°C)	20	2	2	5	8
5	Handpieces 270F	269.6°F (132°C)	4	22	26	5 units	5 units

The steam for the sterilization process is produced by warming up a controlled amount of demineralized water that is inserted into a pipe heating element and then flows into the chamber as steam. This technique is used as a way of reducing water consumption and saving energy. The autoclave is equipped with a heating element wrapped around the chamber to maintain the required temperatures and steam for the sterilization process. All of these processes are done via the computerized control system of the device.

The door's locking mechanism is designed to allow closing/opening the door, easily, with one hand.

The chamber door has the following features protecting personnel from hazards:

- One door micro-switch that indicate that the door is closed. Without this indication steam is not introduced into the chamber. The micro-switch prevents opening the door while the chamber is pressurized and at the end of cycle until chamber pressure equalizes to room pressure.
- An electrical door locking pin that blocks door opening during cycle operation.

In addition, the following safety devices are installed in the autoclave to optimize its safe operation:

- A safety thermostat to prevent over-heating of the chamber heating elements.
- A safety cut-off switch to prevent over heating of the pipe heating element.
- A pressure safety valve to prevent over-pressurizing of the chamber.

The T-Top 10 autoclave has one configuration only, whereas T-Top 11 has two configurations (available upon request) - a manually filled reservoir of demineralized water or an automatic / direct inlet of demineralized water from the water supply system. The T-Top 10 has a manually filled reservoir of demineralized water only.

There is a demineralized water overflow outlet at the rear, and a demineralized water overflow, and wastewater outlet is located on front.

Automatic water quality checking will alert the user of poor water quality, protecting the autoclave chamber from corrosive minerals found in poor quality water.

The T-Top 10 & T-Top 11 feature a built-in memory to record up to 500 sterilization cycles. The T-Top 10 & T-Top 11 have a built-in USB port to enable exporting this data to a USB device, to be transferred to a PC.

The built-in USB port also enables the operation of an external, optional barcode printer, by using a dedicated cable - the barcode printer can print labels with a unique cycle ID barcode, operator's name, sterilization and expiry dates. One barcode printer can be connected to the machine.

There is Wi-Fi connection available to customers (optional). If the unit is connected to Wi-Fi, this enables remote diagnostics and issue resolution from Tuttnauer. The software has been validated and cybersecurity has been considered for this option – see software reports in the 510(k) file.

The chamber is made of a corrosion-resistant 304L stainless steel, and the door is made of corrosion-resistant 304L stainless steel. The outer covers are made of polycarbonate.

The properties of the T-Top 10 & T-Top 11 are as described in the following table:

Table 4: T-Top 10 & T-Top 11 properties

Property			Value	
			T-Top 10	**T-Top 11**
External size	Width		~18” (46.2 cm)	~19.5” (49.7 cm)
	Height		~18” (46 cm)	~17.5” (44.7 cm)
	Depth		~23.5" (58.5 cm) (supporting common install base carry a ~23" (60 cm) countertop)	
Chamber	Diameter		~9.8” (249 cm)	~11” (28 cm)
	Depth		~17.7” (45 cm)	~17.7” (45.2 cm)
	Volume		~732 Ounces (20.8 Lit)	~936 Ounces (26.6 Lit)
	Usable chamber space		75% (~549 Ounces/~15.6 Lit)	75% (~685 Ounces/~20 Lit)
Max. Allowable Working pressure (MAWP)			~40.6 PSI (2.8 bar)	
Safety relief valve			~40 PSI (2.8 bar)	
Net weight			~99 lbs (45 kg)	~115 lbs (52 kg)
Shipping weight			~112 lbs (51 kg)	~125.6 lbs (57 kg)
Floor loading requirements			~165 lbs (75 kg)	
Max load	Solid /Unwrapped		~13 lbs (6 kg)	~19.8 lbs (9 kg)
	Solid /Wrapped		~7.7 lbs (3.5 kg)	~11.9 lbs (5.4 kg)
	Textile		~3.3 lbs (1.5 kg)	~4.4 lbs (2 kg)
Maximum load per tray	Unwrapped		~2.67 lbs (1.2 kg)	~4 lbs (1.8 kg)
	Wrapped		~1.6 lbs (0.72 kg)	~2.4 lbs (1.08 kg)
Tray dimensions			~14.7” x ~7.3” x ~0.6” (37.5 cm x 18.5cm x 1.5 cm)	~14.7” x ~8.14” x ~0.6” (37.5 cm x 20.7cm x 1.5 cm)
No. of trays			4	
Mineral-free water reservoir		Max. water volume	~122 Ounces (3.6 Lit) Overflow ~237 Ounces (7 Lit)	
		Min. water volume	~45.6 Ounces (1.35 Lit) (up to the float)	
Used (waste) water reservoir		Max. water volume	~127 Ounces / (3.75 Lit) – up to float ~182.5 Ounces (182.5 Lit.) - overflow	
Load No. counter			Counting from 0 to 500 and nullifies	

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.

5. LIST OF DEVICES

Table 5: List of devices models in the current submission

Device model	Device catalogue no.	Device description
T-Top 10 230V PED / ASME	T-Top-10-230V-PED / ASME	An autoclave with a 10” diameter chamber and with a volume of 20.8L (~732 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir.
T-Top 10 120V PED / ASME	T-Top-10-120V-PED / ASME	An autoclave with a 10” diameter chamber and with a volume of 20.8L (~732 Oz), operating in 120V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir.
T-Top 11 230V PED / ASME	T-Top-11-230V-PED / ASME	An autoclave with a 11” diameter chamber and with a volume of 26.6L (~936 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir. There is also an option to have automatic filled via demineralized water inlet.

Device model	Device catalogue no.	Device description
T-Top 11 120V PED / ASME	T-Top-11-120V-PED / ASME	An autoclave with a 11" diameter chamber and with a volume of 26.6L (~936 Oz), operating in 120V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir. There is also an option to have automatic filled via demineralized water inlet.

* All products if provided with a Printer will have a -P at the end of the product catalogue number.

6. INDICATION FOR USE

The T-Top 10 & T-Top 11 tabletop autoclaves are designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical & dental offices).

The T-Top 10 and T-Top 11 devices are validated for use in:

- Unwrapped instruments, wrapped instruments and dental handpieces (Class S cycles).
- Unwrapped instruments, wrapped instruments, sterilizing dental handpieces and textiles/porous loads (Class B cycles).

Intended user

The T-Top 10 & T-Top 11 Table-Top autoclave 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 T-Top family (T-Top 10 & T-Top 11) and the cleared predicate devices, the T-Edge 10 and T-Edge 11:

- General design of device: chamber volume, control system;
- Indication for use and intended users
- Materials;
- Energy source;
- Performance;
- Sterilization parameters

Reason for the 510(k):

Modification of a legally marketed device that would not otherwise qualify for a Special 510(k)**.** The T-Top 10 & T-Top 11 are class II device, equivalent to the predicate cleared devices, T-Edge 10 and T-Edge 11 (K213080) but changes made exceeds the limitations for a special 510(k) and thus the device requires a traditional 510(k).

The Operating system of T-Top devices is based on Linux (using Java as the programing language) which is the same as in the predicate device T-Edge.

The T-Top 10 and T-Top 11 offers a half-load cycle with adjusted drying time, whereas the T-Edge 10 and T-Edge 11 does not have this cycle.

The chamber volume of the T-Top 10 corresponds to the 10” chamber. It is different as the T-Edge 10 holds for 23L whereas the T-Top 10 holds 20.8L. The chamber volume of the T-Top 11 corresponds to the 11” chamber. It is different as the T-Edge 11 holds for 27.2L whereas the T-Top 11 holds 26.6L.

Table 6: Comparison of technological characteristics with predicate devices

Parameter	T-Edge K213080	T-Top	Comparison
Chamber volume	This device is a single door table-top autoclave with a chamber volume of:	This device is a single door table-top autoclave with a chamber volume of:	Different.

Parameter	T-Edge K213080	T-Top	Comparison
	23L (~778 ounces) for the T-Edge 10 27.2L (~913 ounces) for the T-Edge11.	20.8L (~732 ounces) for the T-Top 10 26.6L (~936 ounces) for the T-Top 11.	The 10" T-Edge holds 23L whereas the 10" T-Top holds 20.8L The 11" T-Edge holds 27.2L whereas the 11" T-Top holds 26.6L
Control system	The device is software controlled with electronic control panel that permits automatic usage.	The device is software controlled with electronic control panel that permits automatic usage.	Same
	The device is non-programmable.	The device is non-programmable.	Same
	The Operating system is Linux (programing language is Java).	The Operating system is Linux (programing language is Java).	Same
Indication for use	The T-Edge 10 & T-Edge 11 are tabletop autoclaves designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices).	The T-Top 10 & T-Top 11 are tabletop autoclaves designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical and dental offices).	Same

Parameter	T-Edge K213080	T-Top	Comparison
Materials	The outer cover of the device is made of polycarbonate.	The outer cover of the device is made of polycarbonate.	Same
	The chamber is made of 316L stainless steel.	The chamber is made of 304L stainless steel.	Different. 304L is a different grade of stainless steel however the material holds the required properties for an autoclave chamber.
	The door is made of 304L stainless steel.	The door is made of 304L stainless steel.	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
Performance	The operation principle is sterilization by heating a controlled amount of demineralized water to generate steam as the sterilization reagent and maintaining its temperature by using a heating element surrounding the chamber. The water is	The operation principle is sterilization by heating a controlled amount of demineralized water to generate steam as the sterilization reagent and maintaining its temperature by using a heating element surrounding the chamber. The water is	Same

Parameter	T-Edge K213080	T-Top	Comparison
	drawn from a built-in water reservoir.	drawn from a built-in water reservoir.	
	The heating of the water to generate the steam is done by using a water pipe heater and the heating element used is metal jacket.	The heating of the water to generate the steam is done by using a water pipe heater and the heating element used is metal jacket.	Same
	The T-Edge 10 & T-Edge 11 have a vacuum mechanism to allow better air removal of air pockets in the load for an effective sterilization (i.e., pre-vacuum) and to allow drying of the load at the end of the sterilization process. This possibility exists as the T-Edge 10 & T-Edge 11 can be switched between S-class cycles and B-class cycles.	The T-Top 10 & T-Top 11 have a vacuum mechanism to allow better air removal of air pockets in the load for an effective sterilization (i.e., pre-vacuum) and to allow drying of the load at the end of the sterilization process. This possibility exists as the T-Edge 10 & T-Edge 11 can be switched between S-class cycles and B-class cycles.	Same
Sterilization parameters	The T-Edge 10 & T-Edge 11 have both Class-B and Class-S cycles and it can be switched between modes. The sterilization parameters for the Class-B cycles (see Table 1 Section 4 in this document):	The T-Top 10 & T-Top 11 have both Class-B and Class-S cycles and it can be switched between modes. The sterilization parameters for the Class-B cycles (see Table 1 Section 4 in this document):	Same

Parameter	T-Edge K213080	T-Top	Comparison
	– Unwrapped instruments: temp. 134°C/273.2°F for 4 minutes. – Wrapped pouches: temp. 134°C/273.2°F for 4 minutes. – Unwrapped delicate: temp. 121°C/249.8°F for 20 minutes. – Wrapped delicate: temp. l21°C/249.8°F for 20 minutes. The sterilization parameters for the Class-S cycles (see Table 2 Section 4 in this document): – Unwrapped instruments: temp. 132°C/269.6°F for 4 minutes – Wrapped pouches: temp. 132°C/269.6°F for 4 minutes – Unwrapped delicate: temp. 121°C/249.8°F for 20 minutes	– Unwrapped instruments: temp. 134°C/273.2°F for 4 minutes. – Wrapped pouches: temp. 134°C/273.2°F for 4 minutes. – Unwrapped delicate: temp. 121°C/249.8°F for 20 minutes. – Wrapped delicate: temp. l21°C/249.8°F for 20 minutes. The sterilization parameters for the Class-S cycles (see Table 2 Section 4 in this document): – Unwrapped instruments: temp. 132°C/269.6°F for 4 minutes – Wrapped pouches: temp. 132°C/269.6°F for 4 minutes – Unwrapped delicate: temp. 121°C/249.8°F for 20 minutes	

Parameter	T-Edge K213080	T-Top	Comparison
	– Handpieces: temp. l32°C/269.6°F for 4 minutes	Handpieces: temp. l32°C/269.6°F for 4 minutes	

8. PERFORMANCE TESTING

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 • FCC part 15, subpart B	Pass
Software validation	Verifying that the SW used meets standard requirements	Meeting standard specification	• IEC 62304-2006+A1:2015	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 dynamic air removal sterilizers)	The Bowie-Dick test indicator sheet shall show a uniform color change	• ANSI/AAMI ST-55	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-55	Pass
Empty chamber tests (250F/273F)	to ensure that	The temperature shall not exceed	• ANSI/AAMI ST-55	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
– on wrapped and unwrapped load	the sterilizer is capable of providing steady-state thermal conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load	more than 3°C above the sterilization temperature. The temperature shall not be below the sterilization temperature Actual exposure time		
Full chamber load test (250F/273F) – on wrapped and unwrapped 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-55	Pass
Biological performance with a textile PCD	Verifying biological performance	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-55	Pass
Biological performance with wrapped instrument PCD	Verifying biological performance	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-55	Pass
Biological performance with dental handpieces	Verifying biological performance	There shall be no growth observed in the vials containing turbines or in the extraction of any of the turbines, except	• ANSI/AAMI ST-55	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
		for the positive controls. 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, T-Top 10 & T-Top 11, are as safe, as effective, and performs as well as or better than the legally marketed device