January 4, 2022

Tuttnauer Ltd.
Robert Basile
Official Correspondent
Har-Tuv Industrial Zone
Beit-Shemesh, Jerusalem 9910101
Israel

Re: K213080
Trade/Device Name: T-Edge 10, T-Edge 11
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 23, 2021
Received: September 23, 2021

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,

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
K213080

Device Name
T-Edge 10 & T-Edge 11

Indications for Use *(Describe)*

The T-Edge 10 & T-Edge 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 and dental offices).

The T-Edge 10 & T-Edge 11 are validated for use in:
- Sterilizing fabric packs / textiles
- Sterilizing dental handpieces

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

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.

Indications for Use

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]
1	Unwrapped Instr. 273F	273.2°F (134°C)	4	2	6	9
2	Wrapped Pouches 273F	273.2°F (134°C)	4	20	Instruments – 3.6	Instruments – 5.4
					Textile – 1.5	Textile – 2
					Handpieces – 1 units	
3	Unwrapped Delicate 250F	250°F (121°C)	20	2	6	9
4	Wrapped Delicate 250F	250°F (121°C)	20	30	Instruments – 3.6	Instruments – 5.4
					Textile – 1.5	Textile – 2
5	B&D Test	273.2°F (134°C)	3.5	2	-	-
6	Vacuum Test	NA	NA	NA	-	-

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]
1	Unwrapped instruments 270F	269.6°F (132°C)	3	2	5	8
2	Wrapped instruments pouches 270F	269.6°F (132°C)	4	30	3.6	4.5
3	Unwrapped delicate instruments 250F	249.8°F (121°C)	20	2	5	8
4	Handpieces 270F	269.6°F (132°C)	4	30	6 units	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K213080 510(k) Summary
Device name: T-Edge 10 & T-Edge 11

Date Prepared: August 4, 2021

1. SUBMITTER

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2. DEVICE

Trade Name: T-Edge 10 & T-Edge 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: Tuttnauer's Elara 11 autoclave
Secondary predicate: Tuttnauer's EZ11Plus autoclaves

Predicate name	Product Code	Regulation Number	Regulation Name	Class	510K no.
Elara 11	FLE	21CFR 880.6880	Steam Sterilizer	Class II	K143311
EZ11Plus	FLE	21CFR 880.6880	Steam Sterilizer	Class II	K111736

:

4. DEVICE DESCRIPTION

The T-Edge 10 & T-Edge 11 are Table-Top steam sterilizers (autoclave) that use steam as the sterilizing agent. The autoclaves are fully automated device with a computerized control system, which is based on Linux Operating system, that ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and a clear documentation of the sterilization cycle, including the ability of recording the sterilization parameters (with a built-in memory to store history of up-to 999 cycles). A graphical touchscreen is used for monitoring and control purposes.

The T-Edge 10 & T-Edge 11 are Class-B and Class-S devices. They are designed for repeated use of sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities.

The T-Edge 10 & T-Edge 11 are validated for use in:

- Sterilizing fabric packs / textiles
- Sterilizing dental handpieces

The following tables show the cycles that were validated for Class-S and Class-B, 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]
1	Unwrapped Instr. 273F	273.2°F (134°C)	4	2	6	9
2	Wrapped Pouches 273F	(134°C) 273.2°F	4	20	Instruments – 3.6	Instruments – 5.4
					Textile – 1.5	Textile – 2
					Handpieces – 1 units	
3	Unwrapped Delicate 250F	250°F (121°C)	20	2	6	9
4	Wrapped Delicate 250F	250°F (121°C)	20	30	Instruments – 3.6	Instruments – 5.4
					Textile – 1.5	Textile – 2
5	B&D Test	273.2°F (134°C)	3.5	2	-	-
6	Vacuum Test	NA	NA	NA	-	-

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]
1	Unwrapped instruments 270F	269.6°F (132°C)	3	2	5	8
2	Wrapped instruments pouches 270F	269.6°F (132°C)	4	30	3.6	4.5
3	Unwrapped delicate instruments 250F	249.8°F (121°C)	20	2	5	8
4	Handpieces 270F	269.6°F (132°C)	4	30	6 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 T-Edge 10 & T-Edge 11 autoclaves are equipped with a built-in vacuum pump used for fractionated pre-vacuum air removal at the first stage of the cycle, eliminating air pockets from all load types, including porous load and most kinds of tubes (rubber, plastic etc.). This is maximizing efficient steam penetration throughout the entire load, resulting in temperature uniformity and an effective sterilization. After the sterilization stage the vacuum pump is used for post-vacuum drying, performed with the door closed.

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:

- Two door micro-switches that indicate that the door is closed and locked. Without this indication steam is not introduced into the chamber. These micro-switches prevent 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 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-Edge 10 & T-Edge 11 autoclaves have two optional 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 demineralized water overflow outlet is located on the rear cover, demineralized water overflow, and wastewater outlet on the rear cover. Built-in system for checking water quality 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-Edge 10 & T-Edge 11 feature a built-in memory to record up to 999 sterilization cycles. The T-Edge 10 & T-Edge 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. The device also has a built-in network port (LAN) for use with optional Tuttnauer's R.PC.R software.

The chamber is made of a corrosion-resistant 316L 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-Edge 10 & T-Edge 11 are as described in the following table:

Table 3: T-Edge 10 & T-Edge 11 properties

Property		**Value**	
		T-Edge 10	**T-Edge 11**
External size	Width	~19" (48 cm)	~19.7" (50 cm)
	Height	~19.7" (50 cm)	

Property			Value	
			T-Edge 10	T-Edge 11
	Depth		~22.8" (58 cm) (supporting common install base carry a ~23" (60 cm) countertop)	
Chamber	Diameter		~10” (25 cm)	~11” (28 cm)
	Depth		~18” (46 cm)	
	Volume		~778 Ounces (23 Lit)	~913 Ounces (27.2 Lit)
	Usable chamber space		75% (~575 Ounces/~17 Lit)	75% (~685 Ounces/~20.5 Lit)
Max. Allowable Working pressure (MAWP)			~40.6 PSI (2.8 bar)	
Safety relief valve			~40 PSI (2.8 bar)	
Net weight			~117 lbs (53 kg)	~124 lbs (56 kg)
Shipping weight			~145 lbs (66 kg)	~152 lbs (69 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			~16.6” x ~7.4” x ~0.8” (42.1 cm x 18.9 cm x 2.05 cm)	~16.6” x ~8.14” x ~0.8” (42.1 cm x 20.7 cm x 2.05 cm)
No. of trays			5	
Mineral-free water reservoir		Max. water volume	Overflow (up to the float): ~128 Ounces (3.8 Lit)	
		Min. water volume	~33.8 Ounces (1 Lit)	
		The volume used by the sterilization cycle/load having the highest steam consumption	Recorded 27 Ounces (800 ml) were required to sterilize full load of porous type using "wrapped 121"	~30 Ounces (~900 ml) for Wrapped 273°F + virus protect
Used (waste) water reservoir		Max. water volume	Max vol.: ~135 Ounces / (4 Lit) Float: ~125 Ounces (3.7 Lit.) max allowed for start cycle	

Property	Value	
	T-Edge 10	T-Edge 11
Load No. counter	Counting from 0 to 999 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

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

Table 4: List of devices models in the current submission

Device model	Device catalog no.	Device description
T-Edge 10 230V	AMS10-230-T	An autoclave with a 10” diameter chamber and with a volume of 23L (~778 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir.
T-Edge 10-W 230V	AMS10-230-W-T	An autoclave with a 10” diameter chamber and with a volume of 23L (~778 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied directly via dedicated inlet connected to a demineralized water supply.
T-Edge 10 120V	AMS10-120-T	An autoclave with a 10” diameter chamber and with a volume of 23L (~778 Oz), operating in 120V/1Ph (50/60Hz).

Device model	Device catalog no.	Device description
		The demineralized water is supplied by a manually filled reservoir.
T-Edge 10-W 120V	AMS10-120-W-T	An autoclave with a 10” diameter chamber and with a volume of 23L (~778 Oz), operating in 120V/1Ph (50/60Hz). The demineralized water is supplied directly via dedicated inlet connected to a demineralized water supply.
T-Edge 11 230V	AMS11-230-T	An autoclave with a 11” diameter chamber and with a volume of 27.2L (~913 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir.
T-Edge 11-W 230V	AMS11-230-W-T	An autoclave with a 11” diameter chamber and with a volume of 27.2L (~913 Oz), operating in 230V/1Ph (50/60Hz). The demineralized water is supplied directly via dedicated inlet connected to a demineralized water supply.
T-Edge 11 120V	AMS11-120-T	An autoclave with a 11” diameter chamber and with a volume of 27.2L (~913 Oz), operating in 120V/1Ph (50/60Hz). The demineralized water is supplied by a manually filled reservoir.

Device model	Device catalog no.	Device description
T-Edge 11-W 120V	AMS11-120-W-T	An autoclave with a 11” diameter chamber and with a volume of 27.2L (~913 Oz), operating in 120V/1Ph (50/60Hz). The demineralized water is supplied directly via dedicated inlet connected to a demineralized water supply.

6. INDICATION FOR USE

The T-Edge 10 & T-Edge 11 table-top autoclaves are designed for 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-Edge 10 & T-Edge 11 are validated for use in:

- Sterilizing fabric packs / textiles
- Sterilizing dental handpieces

Intended user

The T-Edge 10 & T-Edge 11 Table-Top autoclave are intended for use by trained personnel in hospital and healthcare settings.

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-Edge family (T-Edge 10 & T-Edge 11) and the cleared predicate devices, the Elara11 (the primary predicate) and the EZ11Plus (The secondary predicate):

- 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):

The T-Edge 10 & T-Edge 11 are class II device, equivalent to the predicate cleared devices, Elara11 (K143311) and EZ11plus (K111736) 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-Edge devices is based on Linux (using Java as the programing language) compared to Windows (using C# as the programing language) in the predicate devices.
- The sterilization time for the Unwrapped delicate cycle in the T-Edge 10 & T-Edge 11 is 10 minutes shorter than its equivalent in the EZ11 (20 minutes as compared to 30 minutes).
- The chamber volume of the T-Edge 10 corresponds to the 10” chamber. It differs in 23L compared to 28.5L. The chamber volume of the T-Edge 11 corresponds to the 11” chamber. It differs slightly in 27.2L compared to 28.5L.

Table 5: Comparison of technological characteristics with predicate devices

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
Chamber volume	This device is a single door table-top autoclave with a chamber volume of 28.5L.	This device is a single door table-top autoclave with a chamber volume of 28.5L.	This device is a single door table-top autoclave with a chamber volume of: 23L (~778 ounces) for the T-Edge 10	Different

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
			27.2L (~913 ounces) for the T-Edge11.	
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.	The device is software controlled with electronic control panel that permits automatic usage.	Same
	The device is non-programmable.	The device is non-programmable.	The device is non-programmable.	Same
	The Operating system is Windows (programing language is C#).	The Operating system is Windows (programing language is C#).	The Operating system is Linux (programing language is Java).	Different
Indication for use	The Elara11 is a tabletop autoclave designed for the sterilization of 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	The EZ11Plus is a tabletop autoclave designed for the sterilization of 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,	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,	Different

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
	clinics, and in first aid rooms.	dental, medical clinics, and in first aid rooms and in small laboratories.	clinics, and medical and dental offices).	
Materials	The outer cover of the device is made of metal (aluminum).	The outer cover of the device is made of metal (aluminum).	The outer cover of the device is made of polycarbonate.	Different
	The chamber is made of 316L stainless steel.	The chamber is made of 316L stainless steel.	The chamber is made of 316L stainless steel.	Same
	The door is made of 304L stainless steel.	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).	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	The operation principle is sterilization by heating a controlled amount of demineralized water to generate steam as the sterilization reagent and maintaining its	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	Same

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
	temperature by using a heating element surrounding the chamber. The water is drawn from a built-in water reservoir.	temperature by using a heating element surrounding the chamber. The water is drawn from a built-in water reservoir.	using a heating element surrounding the chamber. The water is drawn from a built-in water reservoir.	
	The heating of the water to generate the steam is done in a steam generator and the heating element used is metal band.	The heating of the water to generate the steam is done in a steam generator and the heating element used is metal band.	The heating of the water to generate the steam is done by using a water pipe heater and the heating element used is silicon jacket.	Same
	The Elara11 has a vacuum mechanism to allow better air removal of air pockets in the load for an effective sterilization before the start of the sterilization process (i.e., pre-vacuum) and to allow drying of the load at the end of the sterilization process.	The EZ11Plus has no vacuum mechanism	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.	Same as the Elara 11 (primary predicate).

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
Sterilization parameters	The Elara11 has 6 key programs as a **Class-B** device. The sterilization parameters are as follows: – Unwrapped instruments: temp. 134°C/273°F for 4 minutes. – Wrapped instruments: temp. 134°C/273°F for 4 minutes. – Unwrapped delicate instruments: temp. 121°C/250°F for 20 minutes. – Wrapped delicate instruments: temp. l21°C/250°F for 20 minutes.	The EZ11Plus has 4 key programs as a **Class-S** device. The sterilization parameters are as follows: – Unwrapped instruments: temp. 132°C for 3 minutes – Wrapped instruments, pouches: temp. 132°C for 4 minutes – Unwrapped delicate instruments: temp. 121°C for 30 minutes – Handpieces: temp. l32°C for 4 minutes	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): – Unwrapped instruments: temp. 134°C/273.2°F for 4 minutes. – Wrapped pouches[1]: 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):	Same for the Elara11. Different for the EZ11Plus.

Parameter	Elara11 - K143311	EZ11Plus - K111736	T-Edge	Comparison
			– Unwrapped instruments: temp. 132°C/269.6°F for 3 minutes – Wrapped pouches: temp. 132°C/269.6°F for 4 minutes – Unwrapped delicate: temp. 121°C/249.8°F for 20 minutes – Handpieces: temp. l32°C/269.6°F for 4 minutes	

Notes:

1. The Wrapped pouches cycle in the T-Edge is equivalent to the Wrapped instruments cycle in the Elara11.

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 • FCC part 15, subpart B	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
Software validation	Verifying that the SW used meets standard 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 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) – 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
Full chamber load test (250F/273F) – on wrapped and unwrapped load	to ensure that the sterilizer is capable of providing steady-state thermal	The temperature shall not exceed more than 3°C above the sterilization temperature.	• ANSI/AAMI ST-55	Pass

Test name	Purpose	Acceptance criteria	Standards used	Results (Pass / No Pass)
	conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load	The temperature shall not be below the sterilization temperature Actual exposure time		
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 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.	• ANSI/AAMI ST-55	Pass

9. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device, T-Edge 10 & T-Edge 11, are as safe, as effective, and performs as well as or better than the legally marketed device