October 30, 2026

Zhejiang Fomos Medical Technology Co., Ltd.
℅ Indre Larson
Senior Regulatory Consultant
Sterling Medical Devices, LLC dba Vantage MedTech
160 Chubb Ave.
Suite 301
Lyndhurst, New Jersey 07071

Re: K260354
Trade/Device Name: Foster Plus-22L (SNK/CE-F22)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: February 3, 2026
Received: February 3, 2026

Dear Indre Larson:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.10.30 17:19:18 -04'00'

Stephen Anisko
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260354

Device Name
Foster Plus-22L (SNK/CE-F22)

Indications for Use *(Describe)*

Foster Plus-22L tabletop autoclave is designed for the sterilization of medical and surgical goods such as wrapped 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).
Foster Plus is validated for use in:
• Wrapped instruments and dental handpieces (Class S cycles).
• Wrapped instruments, sterilizing dental handpieces and textiles/porous loads (Class B cycles).

Cycle Name	Sterilization Temperature °C	Sterilization Time (min)	Drying Time (min)	Type of Load and Maximum Load
134°C Universal Class B	134	4	20	Wrapped Tools – 6.075kg Textile – 0.905kg
134°C Fast Class S	134	4	20	Wrapped Tools – 6.075kg Textile – 0.905kg
121°C Universal Class B	121	20	20	Wrapped Tools – 6.075kg Textile – 0.905kg
121°C Fast Class S	121	20	20	Wrapped Tools – 6.075kg Textile – 0.905kg
B&D Test	134	3.5	2	/

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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510(k) Summary (K260354)

Foster Plus-22L

Submitter: Mr My G Tran
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China

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1. Device

Trade Name: Foster Plus-22L (SNK/CE-F22)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Common Name: Electronic autoclave
Classification Name: Steam Sterilizer
Review Panel: General Hospital
Product Code: FLE

2. Predicate Device:

Trade Name T-Top (T-Top 10); T-Top (T-Top 11)
510(k) Submitter / Holder TUTTNAUER LTD.
510(k) Number K232658
Regulation Number 21 C.F.R. 880.6880
Classification Class II
Classification Panel General Hospital
Product Code FLE

3. Device Description

Foster Plus-22L is an autoclave with a real time display that shows all data during the sterilization cycle. With auto diagnose function, protection against overheating or over pressurizing, and thus ensures reliability of the sterilization results. A built-in condenser water collecting system prevents discharge of waste steam and keeps the machine clean and safe. Foster Plus-22L uses the advanced technology of 3 times pre-vacuum and vacuum drying. It enables the hot steam to penetrate into thin tube and porous material. This product is suitable for dentistry, ophthalmology, surgical instruments, dressing theatres and laboratories.

Foster Plus-22L dynamic-air-removal steam-heated sterilizers that are using steam as the sterilizing agent, for the purpose of sterilizing heat stable medical devices: wrapped solids, hollow and porous products.

Foster Plus-22L has a manual door and is designed to be a fast cycle sterilizer that is mobile and can operate independent of building water utilities due to its internal water reservoirs.

A built-in 1500 kW steam generator is used to supply the steam for the sterilization process.

The autoclave has multiple cycles equipped with a vacuum system that allows:

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

The autoclave model Foster Plus-22L stand-alone devices that do not need to interact with other devices or to interact with any person(s) or patient(s) besides the current device operator.

The following tables show the properties for Foster Plus-22L:

Table 1: Properties of Foster Plus-22L.

Property	Foster Plus-22L
Chamber inner dimensions: (Diameter x Depth)	249mm x 450mm
Chamber Volume	0.78 ft^3 (22 liters)
Max. Allowable Working Pressure	37.7 psi (2.6bar)
Net weight	115 lbs. (52kg)

Property	Foster Plus-22L
Shipping weight	137 lbs. (62kg)
Max load	Wrapped Tools – 6.075kg Textile – 0.905kg
Tray dimensions	15 x 7 x 1 in (380 x 188 x 20mm)
Number of trays	3
Load No. counter	Counting from 0 to 65535 then again starts from 0.

Foster Plus-22L offers a choice of automatic programs designed to match the material to be sterilized. The programs included in the device are:

- Programs for Wrapped Loads.
- Two Test Programs: Bowie & Dick Test, the Vacuum Test.

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

For process documentation, the information concerning the cycles is printed from an integrated printer. Both models feature a built-in memory to record up to 280000 sterilization cycles.

The following table show the preprogrammed cycles for Foster Plus-22L.

Table 2: standard cycles for Foster Plus-22L

Cycle Name	Sterilization Temperature (°C)	Sterilization Time (min)	Pre-vacuum	Working pressure (bar)	Drying Time (min)	Maximum Load
134°C Universal Class B	134	4	3 times	2.1	20	Wrapped Tools – 6.075kg Textile – 0.905kg
134°C Fast Class S	134	4	1 time	2.1	20	Wrapped Tools – 6.075kg Textile – 0.905kg
121°C Universal Class B	121	20	3 times	1.1	20	Wrapped Tools – 6.075kg Textile – 0.905kg

Cycle Name	Sterilization Temperature (°C)	Sterilization Time (min)	Pre-vacuum	Working pressure (bar)	Drying Time (min)	Maximum Load
121°C Fast Class S	121	20	1 time	1.1	20	Wrapped Tools – 6.075kg Textile – 0.905kg
B&D	134	3.5	3 times	2.1	2	N/A
Leak and Vacuum Test	N/A	N/A	N/A	N/A	N/A	N/A

4. Indications for Use

Foster Plus-22L tabletop autoclave is designed for the sterilization of medical and surgical goods such as wrapped 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).
Foster Plus is validated for use in:

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

Cycle Name	Sterilization Temperature °C	Sterilization Time (min)	Drying Time (min)	Type of Load and Maximum Load
134°C Universal Class B	134	4	20	Wrapped Tools – 6.075kg Textile – 0.905kg
134°C Fast Class S	134	4	20	Wrapped Tools – 6.075kg Textile – 0.905kg
121°C Universal Class B	121	20	20	Wrapped Tools – 6.075kg Textile – 0.905kg
121°C Fast Class S	121	20	20	Wrapped Tools – 6.075kg Textile – 0.905kg
B&D Test	134	3.5	2	/

5. Summary of Device Technological Characteristics:

. The following table summarizes the similarities and differences between the subject and predicate devices.

Table 3 Technological Characteristics Comparison

Technical Characteristics	Subject Device K260354	Predicate Device (K232658)	Discussion of Differences
Trade Name	Foster Plus-22L	T-Top (T-Top 10); T-Top (T-Top 11)	N/A

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Manufacturer	Zhejiang Fomos Medical Technology Co.,Ltd.	TUTTNAUER LTD.	N/A
Device Type	Sterilizer, Steam	Sterilizer, Steam	Identical
Product Code	FLE	FLE	Identical
Classification Regulation	21 C.F.R. § 880.6880	21 C.F.R. § 880.6880	Identical
Class	II	II	Identical
Patient Population	Not specified	Not specified	Identical

<table>
<tr>
<td>Indications for Use</td>
<td>Foster Plus-22L tabletop autoclave is designed for the sterilization of medical and surgical goods such as wrapped 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).
Foster Plus-22L is validated for use in:
• Wrapped instruments and dental handpieces (Class S cycles).
• Wrapped instruments, sterilizing dental handpieces and textiles/porous loads (Class B cycles).
<table>
<tr><th>Cycle Name</th><th>Sterilization Temperature °C</th><th>Sterilization Time (min)</th><th>Drying Time (min)</th><th>Type of Load and Maximum Load</th></tr>
<tr><td>134°C Universal Class B</td><td>134</td><td>4</td><td>20</td><td>Wrapped Tools – 6.075kg
Textile – 0.905kg</td></tr>
<tr><td>134°C Fast Class S</td><td>134</td><td>4</td><td>20</td><td>Wrapped Tools – 6.075kg
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Textile – 0.905kg</td></tr>
<tr><td>B&D Test</td><td>134</td><td>3.5</td><td>2</td><td>/</td></tr>
</table>
</td>
<td>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).</td>
<td>Similar
Sterilization cycle parameters are different from the subject device.</td>
</tr>
</table>

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Environment of Use	Hospital and other healthcare setting.	Hospital and other healthcare setting.	Identical
User Control	The operation of the autoclave is done via integrated keypad located next to the screen. The autoclave contains user accessible clean water tank, USB port, power switch, connector to the printer, door handle, used water outlet and clean water outlet. The device is non-programmable. The device does not connect to PC or other devices.	The device is software controlled with electronic control panel that permits automatic usage. The device is non-programmable. The Operating System is Linux (Programming language is Java)	Different, the subject device does not connect to external computers.
Integrated Printer	Present	Present	Identical
Materials	The outer cover of the device is made of ABS and Cold rolled steel sheet. The chamber is made of SUS304. The door is made of SUS304.	The outer cover of the device is made of polycarbonate. The chamber is made of 304L stainless steel. The door is made of 304L stainless steel.	Similar. The SUS304 is a different grade of stainless steel however the material holds the required properties for an autoclave chamber.
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).	Identical

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
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 loop surrounding the chamber. The water is drawn from a built-in water reservoir. The heating of the water to generate the steam is done by using a heating rod which is made by of stainless steel. Foster Plus-22L has 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 Foster Plus-22L can be switched between S- class cycles and B- class cycles.	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 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 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.	Similar

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Sterilization Parameters	The Class-B and Class-S cycles and it can be switched between modes. The sterilization parameters for the Class-B cycles: . - Wrapped pouches: temp. 134°C for 4 minutes. - - Wrapped instruments: temp. 121°C for 20 minutes. The sterilization parameters for the Class-S cycles: - Wrapped instruments: temp. 134°C for 4 minutes - Wrapped instruments : temp. 121°C for 20 minutes	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: - 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: - 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 Handpieces: temp. l32°C/269.6°F for 4 minutes	Identical
Electrical Safety	IEC 61010-1:2010 IEC 61010-1:2010/AMD1:2016 IEC 61010-2-040:2020	IEC 61010-1:2010 UL 61010-1:2012 IEC 61010-2-040: 2015	Similar The subject device tested to comply with updated versions of the standards.

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
EMC	EN IEC 61326-1:2021 IEC 61326-1:2020 FCC Part 15 Subpart B	EN 61326-1:2013 IEC 61326-1:2012 FCC part 15, subpart B	Similar The subject device tested to comply with updated versions of the standards.
Software Validation	IEC 62304:2006+A1:2015	IEC 62304:2006+A1:2015	Identical
Pressure vessel testing	ASME Boiler and pressure vessel code, Section VIII division 1	ASME Boiler and pressure vessel code, Section VIII division 1	Identical
Device Performance tests	ANSI/AAMI ST-55	ANSI/AAMI ST-55	Identical
Operating Principle	Steam is the sterilizing agent.	Steam is the sterilizing agent	Identical
External size	• Width: 44cm • Height: 46.5cm • Depth: 62.5cm	T-Top 10 • Width: ~18” (46.2 cm) • Height: ~18” (46 cm) • Depth: ~23.5" (58.5 cm) (supporting common install base carry a ~23" (60 cm) countertop) T-Top 11 • Width: ~19.5” (49.7 cm) • Height: ~17.5” (44.7 cm) • Depth: ~23.5" (58.5 cm) (supporting common install base carry a ~23" (60 cm) countertop)	Similar Difference in external size.

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Chamber	• Diameter: 249mm • Depth: 450mm • Volume: ~744 ounces (22L) • Usable Chamber Space: 75%	T-Top 10 • Diameter: ~9.8" (249 cm) • Depth: ~17.7" (45 cm) • Volume: ~732 Ounces (20.8L) • Usable Chamber Space: 75% T-Top 11 • Diameter: ~11" (28 cm) • Depth: ~17.7" (45.2 cm) • Volume: ~936 Ounces (26.6L) • Usable Chamber Space: 75%	Similar The volume of the chamber for the subject devices is different when compared to the volume of the Predicate device. However, the subject devices are validated with ST55, and the device passed the test.
Max. Allowable Working Pressure (MAWP)	2.6 Bar	~40.6 PSI (2.8 bar)	Similar
Net weight	52kgs	T-Top 10: ~99 lbs (45 kg) T-Top 11: ~115 lbs (52 kg)	Difference in net weight.
Shipping Weight	62kgs	T-Top 10: ~112 lbs (51 kg) T-Top 11: ~125.6 lbs (57 kg)	Difference in shipping weight.
Floor loading requirements	75kg	~165 lbs (75 kg)	Identical

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Max Load	• Wrapped Tools – 6.075kg • Textile – 0.905kg	T-Top 10 • Solid/unwrapped: ~13 lbs (6 kg) • Solid/wrapped: ~7.7 lbs (3.5 kg) • Textile: ~3.3 lbs (1.5 kg) T-Top 11 • Solid/unwrapped: ~19.8 lbs (9 kg) • Solid/wrapped: ~11.9 lbs (5.4 kg) • Textile: ~4.4 lbs (2 kg)	Different. However, the subject devices are validated with ST55, and the device passed the test.
Tray dimensions	380 x 188 x 20mm	T-Top 10: ~14.7”x~7.3”x~0.6” (37.5cmx18.5cmx1.5cm) T-Top 11: ~14.7”x~8.14”x~0.6” (37.5cmx20.7cmx1.5cm)	Different. However, the subject devices are validated with ST55, and the device passed the test.
No. of trays	3	4	Different. However, the subject devices are validated with ST55, and the device passed the test.
Watter Supply	Distilled water is supplied by a manually filled reservoir. There is also an option to have automatic filled via demineralized water inlet.	The demineralized water is supplied by a manually filled reservoir. There is also an option to have automatic filled via demineralized water inlet.	Different. The difference in water source.

Technical Characteristics	**Subject Device** **K260354**	Predicate Device (K232658)	**Discussion of Differences**
Water reservoir	• Max. water volume: 3.5L • Min. water volume: 1L	• 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)	Difference in water reservoir volume.
Used (waste) water reservoir	• 2.5L - up to float • 3.5L - overflow	~127 Ounces / (3.75 Lit) – up to float ~182.5 Ounces (5.39 Lit.) - overflow	Difference use water reservoir volume.
Load No. Counter	Counting from 0 to 65535 and nullifies.	Counting from 0 to 500 and nullifies.	Difference in load number counter.

6. Non-Clinical Testing

The device has passed the following non-clinical testing to verify its safe and effective:

Table 4 Non-clinical Testing

Test name	Test Method	Acceptance criteria	Results
Pressure vessel testing	ASME Boiler and pressure vessel code, Section VIII division 1 compliance testing.	Meeting standard specification	Pass
Sterilizer temperature control	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Biological performance of sterilizers – General Requirements	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Air leaks (pre-vacuum sterilizers)	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass

Moisture retention	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Biological performance of sterilizers – with a textile PCD	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Biological performance of sterilizers – with wrapped instrument PCD	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Biological performance of sterilizers – with dental handpieces	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Mechanical Air Removal – Bowie-Dick test	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Moisture retention – Air leaks	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Moisture retention – Textile test packs	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Moisture Retention – wrapped instrument test trays	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Moisture Retention – Plastic peel pouches	ANSI/AAMI ST55:2016/(R)2023 compliance testing.	Meeting standard specification	Pass
Human Factors Engineering – to demonstrate objective evidence the user	IEC 62366-1:2015+AMD1:2020 EN60601-1-6:2010+A1:2015+A2:2021 compliance testing.	Meeting standard specification	Pass

interface can be used safely.			

7. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective and performs as well as or better than the legally marketed predicate device (K232658).