December 30, 2025

Lucas Lifecare
℅ Dr. Anand Babu Vangala
Manager - Quality & Regulatory
Lourdes Lifecare
No. 1536, 17th B Main,
HBR Layout
Bengaluru, KA 560 043
India

Re: K250168
Trade/Device Name: Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 15, 2025
Received: September 15, 2025

Dear Dr. Anand Babu Vangala:

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.

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 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,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2025.12.30 09:07:48 -05'00'

Stephen Anisko
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K250168

Device Name
Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer

Indications for Use *(Describe)*
Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer is intended to be used in medical, dental, surgical, healthcare, and laboratory applications (e.g hospitals, nursing homes, surgical centers, healthcare clinics, or dental offices) to sterilize heat and moisture-stable reusable loads that are solid, hollow, porous, or delicate, in either wrapped or unwrapped arrangements.

Validated sterilization cycles of LifeUltra include:

Class B cycles
• 134 °C (273 °F) for 4 minutes sterilization with 20 minutes drying – wrapped/unwrapped instruments, hand pieces, textiles, and porous loads (max 7 kg).
• 121 °C (250 °F) for 20 minutes sterilization with 20 minutes drying – delicate or wrapped/unwrapped loads (max 7 kg).

Class S cycles
• 134 °C (273 °F) for 4 minutes sterilization with 20 minutes drying – wrapped/unwrapped instruments and hand pieces (max 7 kg).
• 121 °C (250 °F) for 20 minutes sterilization with 20 minutes drying – delicate loads (max 7 kg).

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.

510(k) Summary K250168

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR 880.6880

Date 510(k)submitted: 26 December-2025.

1. Submitter Information:

Submitter's Name	: Lucas Lifecare
Address	: 2302 Beloit Avenue, Janesville, Wisconsin 53546.
Contact Person	: Joseph Paul, CTO
Telephone Number	: 044 7549 996549, +91 95919-74913
Email	: Joseph@lucaslifecare.com
Official Correspondent	: Anand Babu Vangala, Manager - Quality & Regulatory
Address	: Lourdes Lifecare, No. 1536, 17th B main, HBR Layout, Bengaluru, Karnataka – 560043, India
Tel	: +91 9848188342
Email	: anand@lourdeslifecare.com

2. Trade/ Proprietary Name:

Trade/ Device Name	: Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer
Manufacturer Name	:Lucas Lifecare
Common Name	: Electronic autoclave
Regulation Name	: Steam Sterilizer
Regulation Number	: 21 CFR 880.6880
Primary Product Code	: FLE
Classification Name	: Steam Sterilizer
Regulatory Class	II

3. Legally Marketed Predicate Device Information: (K232658)

Trade/ Device Name	: T-Top (T-Top 11)
Manufacturer Name	: Tuttnauer
Common Name	: Electronic autoclave
Regulation Name	: Steam Sterilizer
Regulation Number	: 21 CFR 880.6880
Primary Product Code	: FLE
Classification Name	: Steam Sterilizer
Regulatory Class	II

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4. Description of Device:

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 autoclave is equipped with a vacuum system, which supports:

- 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

The device has a built-in thermal printer with the following feature:

- The Thermal printer can print the cycle data immediately after cycle completion.
- The print data includes Realtime values of Temperature (°C/°F) and pressure (Bar/kPa) including the overall cycle time.
- The print data also includes overall conditioning time, pressurizing time, sterilization time, and the drying time with the maximum and minimum temperature attained during the sterilization along with the Pass/Fail results.

LifeUltra™ is controlled by a micro-controller with installed software that has pre-set programs to run standard B, S sterilization cycles and test cycles. Saturated steam for sterilization is generated from distilled water, produced in an onboard water distiller, so users can directly tap into municipal facility water. For this feature, the device is programmed to run an automatic water distilling cycle and a manual tank descaling cycle. The integrated software manages the air-water-steam system through precision sensors, probes, and switches that both monitor and control the device's vital parameters in real-time, assuring safe and successful results. The operation of the device is through a back-lit display and control interface.

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

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Table 1: Class B cycles- Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer

#	Cycle Name	Load Type	Sterilization temperature [°F /°C]	Sterilization time [min]	Dry Time[min]	Max load [Kg]
1	B 134 Universal	Unwrapped	273.2°F (134°C)	4	20	7
		Wrapped	273.2°F (134°C)	4	20	Instruments – 4.5
						Textile - 1
						Handpieces -7
2	B 121 Universal	Unwrapped	249.8°F (121°C)	20	20	7
		Wrapped	249.8°F (121°C)	20	20	Instruments – 5.5
						Textile - 1

Table 2: Class S cycles - Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer

#	Cycle Name	Load Type	Sterilization temperature [°F /°C]	Sterilization time [min]	Dry Time [min]	Max load [Kg]
1	S 134 Universal	Unwrapped	273.2°F (134°C)	4	20	7
		Wrapped	273.2°F (134°C)	4	20	Instruments – 4.5
						Textile - 1
						Handpieces - 7
2	S 121 Universal	Unwrapped	249.8°F (121°C)	20	20	7
		Wrapped	249.8°F (121°C)	20	20	Instruments – 5.5
						Textile - 1

Table 3: Test cycles - Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer

#	Cycle Name	Sterilization temperature [°F /°C]	Sterilization time [min]	Dry Time [min]	Max load [Kg]
1	Vacuum Test	NA	NA	NA	-
2	B&D Test	273.2°F (134°C)	3.5	15	-

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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 indicates that the door is closed. Without this indication steam is not introduced into the chamber. An electrical door locking pin that blocks door opening during cycle operation. 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.
- Additionally, a mechanical lock that blocks door opening at positive pressure.

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 thermostat to prevent over-heating of the steam generator.
- A pressure safety valve to prevent over-pressurizing of the chamber.

There is a municipal water inflow input port for up to 500 ppm. There are 2 output ports for demineralized water tank and wastewater tank overflow/drain outlet. The chamber is made of corrosion-resistant 316L stainless steel, and the door is made up of Aluminum Hard Anodized with Teflon coating. The outer covers are made of Carbon Steel with coating.

Table 4: LifeUltra 25L tabletop Mono chamber steam sterilizer properties

Size: Body (Inch)	24'' W x 20'' H x 25'' D
Chamber Dimension	10.8'' Dia x 15.8'' Depth
Chamber Volume	About 25 L
Tray Dimension	15'' x 6.0'' 15'' x 8.5'' 15'' x 9.5'' 15'' x 9'' x 1.6''
Maximum System Work pressure	2.15 bar
Electrical	
Voltage Input	1 Ph /115-125 V
Ampere	18 A
Nominal Power Rating	1950 VA
Frequency	60Hz
Materials	The outer cover of the device is made of Carbon Steel with Teflon coating
	The chamber is made of 316L stainless steel.

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Materials (cont.)	The door is made of Aluminum Hard Anodized with Teflon with Coating
Energy source	• The device can be operated only while connected to an electrical source (the electrical grid). • It has no internal power source (batteries) for device operation. A coin battery is present to store date and time settings and cycle count.
Sterilization parameters	The sterilization parameters for the Class-B cycles (see Table 1 in this document): • B 134 Universal: temp. 134°C/273.2°F for 4 minutes. (Unwrapped, Wrapped) • B 121 Universal: temp. 121°C/249.8°F for 20 minutes. (Unwrapped, Wrapped) The sterilization parameters for the Class-S cycles (see Table 2 in this document): • S 134 Universal: temp. 134°C/273.2°F for 4 minutes. (Unwrapped, Wrapped) • S 121 Universal: temp. 121°C/249.8°F for 20 minutes. (Unwrapped, Wrapped)

5. Indications for Use:

Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer is intended to be used in medical, dental, surgical, healthcare, and laboratory applications (e.g. hospitals, nursing homes, surgical centers, healthcare clinics, or dental offices) to sterilize heat and moisture-stable reusable loads that are solid, hollow, porous, or delicate, in either wrapped or unwrapped arrangements.

Validated sterilization cycles of LifeUltra 25L include:

Class B cycles

- 134 °C (273 °F) for 4 minutes sterilization with 20 minutes drying – wrapped/unwrapped instruments, hand pieces, textiles, and porous loads (max 7 kg).
- 121 °C (250 °F) for 20 minutes sterilization with 20 minutes drying – delicate or wrapped/unwrapped loads (max 7 kg).

Class S cycles

- 134 °C (273 °F) for 4 minutes sterilization with 20 minutes drying – wrapped/unwrapped instruments and hand pieces (max 7 kg).
- 121 °C (250 °F) for 20 minutes sterilization with 20 minutes drying – delicate loads (max 7 kg).

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6. Comparison of Technological Characteristics with Predicate:

Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer has similar design components and operating features as the K232658 predicate device, T-Top (T-Top 11). The following technological characteristics will be compared between the

T-Top 11 and the Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer.

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

Table 5: Comparison of technological characteristics with predicate devices

	Life Ultra 25L Tabletop Mono Chamber Steam Sterilizer	**T-Top (T-Top 11) (K232658)**	**Remarks**
INDICATIONS FOR USE	LifeUltra™ 25L Tabletop Mono Chamber steam Sterilizer is intended to be used in medical, dental, surgical, healthcare, and laboratory applications (e.g. hospitals, nursing homes, surgical centres, healthcare clinics, or dental offices) to sterilize heat and moisture-stable reusable loads that are solid, hollow, porous, or delicate, in either wrapped or unwrapped arrangements.	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).	Same
Size: Body (Inch)	24'' W x 20'' H x 25'' D	19.5" W x 17.5'' H x 23'' D	Similar
Chamber Dimension	10.8'' Dia x 15.8'' Depth	~11" Dia x 17.7" depth	Similar
Chamber Volume	About 25 L	~ 26.6 L	Similar
Tray Dimension	15'' x 6.0'' 15'' x 8.5'' 15'' x 9.5'' 15'' x 9'' x 1.6''	~14.7'' x ~8.14'' x ~0.6''	Similar

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Maximum System Work pressure	2.15 bar	2.8 bar	Similar
Electrical			
Voltage Input	1 Ph/115-125 V	1 Ph/115-125 V	Same
Ampere	18 A	12.5 A	Similar
Nominal Power Rating	1950 VA	1500 VA	similar
Frequency	60Hz	60Hz	Same
Materials	The outer cover of the device is made of Carbon Steel with powder coating	The outer cover of the device is made of polycarbonate.	Different
	The chamber is made of 316L stainless steel.	The chamber is made of 304L stainless steel.	Different
	The door is made of Aluminium Hard Anodized with Teflon Coating	The door is made of 304L stainless steel.	Different
Energy source	The device can be operated only while connected to an electrical source (the electrical grid). It has no internal power source (batteries) for device operation. A coin battery is present to store date and time settings and cycle count.	The device can be operated only while connected to an electrical source (the electrical grid). It has no internal power source (batteries).	Same
Principle of Operation	Moist heat sterilization using saturated steam under pressure	Moist heat sterilization using saturated steam under pressure	Same
Sterilization Parameters	The sterilization parameters for the **Class-B cycles**: • B 134 Universal: temp. 134°C/273.2°F for 4 minutes. (Unwrapped, Wrapped) • B 121 Universal: temp. 121°C/249.8°F for 20 minutes. (Unwrapped, Wrapped) The sterilization parameters for the	The sterilization parameters for the **Class-B** cycles • B 134 Universal: temp. 134°C/273.2°F for 4 minutes. (Unwrapped, Wrapped) • B 121 Universal: temp. 121°C/249.8°F for 20 minutes. (Unwrapped, Wrapped) The sterilization parameters for the **Class-S cycles**: • Unwrapped	Same

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	Class-S: S 134 Universal: temp. 134°C/273.2°F for 4 minutes. (Unwrapped, Wrapped) S 121Universal:temp. 121°C/249.8°F for 20 minutes (Unwrapped, Wrapped)	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	
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 drawn from a built-in water reservoir. The heating of the water to generate the steam is done by using a block heater and the heating element used is cartridge heater. The Life ultra 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 Life Ultra 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 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-Top 11 can be switched between S- class cycles and B-class cycles.	Same

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7. Non-Clinical Test Data:

Testing was performed in accordance with the following international standards:

Standard / Guidance	Title / Description	Edition / Date	Test Result
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (Including Corrigendum 1)	Edition 3.1 (2017-01) Consolidated	Pass
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests	Edition 4.1 (2014 + AMD1:2020) Consolidated	Pass
AAMI / ANSI ST55	Table-top Steam Sterilizers	2016 / (R)2023	Pass
IEC 62304	Medical device software – Software life cycle processes	Edition 1.1 (2015-06) Consolidated	Pass
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	Edition 1.1 (2020-06) Consolidated	Pass
ISO 17665-1	Sterilization of health care products – Moist heat – Requirements for development, validation and routine control of a sterilization process for medical devices	First edition (2024-03)	Pass
IEC TR 60601-4-2	Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and systems	Edition 1.0 (2016-05)	Pass

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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/273 F) 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 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

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Biological performance with a textile PCD, wrapped instrument PCD and dental handpieces	Verifying biological performance	The tested cycle demonstrates a 10^{-6} Sterility Assurance Level (SAL), providing a greater assurance of sterility, when using textile PCDs, wrapped instrument PCDs, and dental handpieces; no growth shall be observed in the vials, or in any biological indicators (BIs), except for the positive controls, where growth shall be observed as expected.	ANSI/ AAMI ST-55	Pass

All tests were performed in accredited laboratories and successfully met the acceptance criteria defined in the respective FDA-recognized consensus standards.

8. Clinical Performance Data:

Clinical testing is not required for this submission.

9. Conclusion:

Based on the comparison of intended use, indications, technological characteristics, principle of operation, and non-clinical performance data, the LifeUltra 25 L Tabletop Mono Chamber Steam Sterilizer performs as well or better than the legally marketed, K232658 predicate device.

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