March 7, 2025

Fort Defiance Industries LLC
Chris Coleman
Quality Management Representative
2411 Maremont Parkway
Loudon, Tennessee 37774

Re: K243801
Trade/Device Name: FRONT-LINE Field Sterilizer (FL135)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: February 12, 2025
Received: February 12, 2025

Dear Chris Coleman:

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: 2025.03.07 16:32:38 -05'00'

for: Christopher K. Dugard
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)*
K243801

Device Name
FRONT-LINE Field Sterilizer (FL135)

Indications for Use *(Describe)*
The Fort Defiance Industries FRONT-LINE Field Sterilizer (FL135) is an autoclave designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities.

CYCLE	MAXIMUM LOAD	EXPOSURE TEMP* (°F/°C)	EXPOSURE TIME (MINUTES)	DRY TIME (MINUTES)
IMMEDIATE USE (IUSS)	25 LBS.	270 / 132	4	0
		275 / 135	3	0
TEXTILES	3 TEXTILE PACKS**	250 / 121	30	15
		270 / 132	4	15
		275 / 135	3	15
WRAPPED INSTR./ POUCHES	25 LBS.	250 / 121	30	35
		270 / 132	4	30
		275 / 135	3	30
HANDPIECES	12 HANDPIECES	270 / 132	4	30
		275 / 135	3	30

NOTES:
* THE ANSI/AAMI ST55:2016 MINIMUM TEMPERATURE IS LISTED FOR ALL CYCLES.
** AAMI STANDARD TEXTILE PACK (9 TOWELS - ST 55 SECTION 5.7.1.1).

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
for
Fort Defiance Industries
FRONT-LINE Field Sterilizer
Model FL135
K243801

Submitter / 510(k) Owner:
Fort Defiance Industries LLC
2411 Maremont Parkway
Loudon, TN 37774
Phone: (865) 408-0100
Fax No: (866) 732-8086

Contact:
Chris Coleman
Quality Management Representative Fort
Defiance Industries LLC
Phone: (865) 657-6108
Fax: (866) 732-8086

Revised: 12 FEB 2025

1. Device Name

Trade Name: FRONT-LINE Field Sterilizer (FL135)

Model Name(s): FL135

Common/usual Name: Electronic autoclave, steam sterilizer

Classification Name: Steam Sterilizer
Class II Device - 21 CFR 880.6880
Product Code FLE

2. Predicate Device

K213457, FRONT-LINE Field Sterilizer, Model FL135, product code FLE, cleared March 2, 2022

3. Description of Device

This change to the FRONT-LINE Field Sterilizer, model FL135, reduces the dry times of the wrapped instrument, textiles, and handpieces cycles from the original dry times to the following new dry times.

Model	Cycle	Exposure Temperature (°F)	Original Dry Time (mins)	New Dry Time (mins)
FL135	Immediate Use Steam Sterilization (IUSS)	270 & 275	0	0
	Textiles	250, 270, & 275	60	15
	Wrapped Instruments/ Pouches	250	60	35
		270 & 275	60	30
	Handpieces	270 & 275	60	30

To allow for the reduction in dry time, the dry rate of the sterilizer was increased by the following changes: (1) added a surface heater on the outside of the chamber to increase heat delivered to the chamber and load, (2) replaced the existing chamber load rack with an improved rack that allows for better heat and mass transfer, (3) implemented a new valve control scheme to improve condensate drainage and air flow during drying, and (4) increased the speed of the air pump to increase airflow through the chamber during drying. FDA consensus standard, AAMI ST55:2016, was referenced to validate dry performance of the predicate and new device. Acceptance criteria were also derived from the above standard.

The Fort Defiance Industries FRONT-LINE Field Sterilizer, model FL135, is an autoclave designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities. The device uses electrical resistive heaters to produce steam as the sterilizing agent. The device adheres to sterilization processes and requirements that are universally accepted sterilization standards for Tabletop Steam Sterilizers. A touchscreen controller is used for monitoring and control of the device.

The device is equipped with multiple safety features. The door includes a safety locking mechanism and door switch. The door switch does not permit cycle operation unless the door is sealed and does not permit the door to be opened until the chamber gauge pressure is near zero. Additional safety features include electronic overtemperature and overpressure protection, independent thermal cutoffs, and a pressure safety relief valve for the chamber.

Only United States Food and Drug Administration cleared sterilization accessories should be used with this autoclave.

4. Design and Materials

The FRONT-LINE Field Sterilizer, model FL135, is a steam sterilizer composed of a stainless-steel chamber, an aluminum chamber door, electric resistive heaters, a plumbing system with a clean water tank, control system, and an aluminum frame providing a housing for all components. The device is electronically controlled and includes 10 pre-programmed sterilization cycles. All materials in the sterilization system and plumbing system are deemed acceptable for steam sterilizers.

5. Technology

The FRONT-LINE FL135 autoclave is a steam sterilizer composed of a pressure vessel that utilizes electric resistive heaters to produce the sterilizing agent, steam, from a chamber boiler. The autoclave contains an electronic control system that automatically initiates programmed Steam Flush Pressure Pulse (SFPP) phases to purge atmospheric air from the chamber followed by a temperature-controlled, timed steam exposure. A final drying phase, assisted by chamber internal and external heaters, completes the sterilization cycle. Exhaust air purged during the dry phase passes through a heat exchanger to condense water vapor and reclaim as much condensate as possible for reuse.

6. Intended Use

The Fort Defiance Industries FRONT-LINE Field Sterilizer (FL135) is an autoclave designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities.

Model	Cycle	Maximum Load	Exposure Temperature[1] (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
FL135	Immediate Use (IUSS)	25 lbs.	270/132	4	0
			275/135	3	
	Textiles	3 Textile Packs[2]	250/121	30	15
			270/132	4	
			275/135	3	
	Wrapped Instruments / Pouches	25 lbs.	250/121	30	35
			270/132	4	30
			275/135	3	
	Handpieces	12 Handpieces	270/132	4	30
			275/135	3	

[1] The ANSI/AAMI ST55:2016 minimum temperature is listed for all cycles.

[2] AAMI Standard Textile Pack (9 towels - ST 55 section 5.7.1.1).

7. Comparison of Technology

The previously cleared device and the FRONT-LINE Field Sterilizer model FL135 are traditional steam sterilizers of similar chamber size using AAMI approved Steam Flush Pressure Pulse (SFPP) dynamic air removal cycles. The previously cleared device and the new FL135 sterilizer use electric heaters to generate steam and touchscreen controllers for cycle control. Based on the information provided below, there are negligible differences noted between the new FL135 and the predicate with regards to chamber size, cycle parameters, and configuration of steam generation. The differences do not affect the safety or effectiveness of the new device compared to the predicate. Table 1 provides a summary of performance and safety characteristics of the proposed new device and the predicate.

Table 1: Comparison of Technology

Performance and/or Safety Characteristic	New Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 K243801	Predicate Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 (K213457)
Indications for Use	The Fort Defiance Industries FRONT-LINE Field Sterilizers are autoclaves designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities.	The Fort Defiance Industries FRONT-LINE Field Sterilizers are autoclaves designed for sterilizing heat- and moisture-stable medical, dental, and surgical materials, including wrapped and unwrapped, solid, porous, and hollow items (e.g., dental handpieces, suction pipes) in healthcare facilities.
Operating Principle	Steam Flush Pressure Pulse (SFPP). Steam is the sterilization agent (traditional method).	Steam Flush Pressure Pulse (SFPP). Steam is the sterilization agent (traditional method).
Performance and Safety Standards Followed	ANSI/AAMI ST55 ASME Sec. VIII Div 1 UL 61010-1 EN 61326-1 UL 61010-2-040	ANSI/AAMI ST55 ASME Sec. VIII Div 1 UL 61010-1 EN 61326-1 UL 61010-2-040

Performance and/or Safety Characteristic	New Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 K243801	Predicate Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 (K213457)
Sterilization Cycles	Factory Pre-Programmed Steam Flush Pressure Pulse (SFPP) Conditioning Phase 30 min exposure @ 250°F Dry time dependent on load 4 min exposure @ 270°F Dry time dependent on load 3 min exposure @ 275°F Dry time dependent on load	Factory Pre-Programmed Steam Flush Pressure Pulse (SFPP) Conditioning Phase 30 min exposure @ 250°F Dry time dependent on load 4 min exposure @ 270°F Dry time dependent on load 3 min exposure @ 275°F Dry time dependent on load
Dry Times - Wrapped	275°F: 30 min 270°F: 30 min 250°F: 35 min	60 min (all temperatures)
Dry Times - Textiles	15 min (all temperatures)	60 min (all temperatures)
Dry Times - Handpieces	30 min (all temperatures)	60 min (all temperatures)
Chamber Size & Volume	**FL135** 13.5” dia. X 24” lg. 2.00 cf. (56.35 L)	**FL135** 13.5” dia. X 24” lg. 2.00 cf. (56.35 L)
Chamber Design and Construction	Single Wall Chamber ASME Section VIII, Div. I certified Stainless steel (316L) chamber and aluminum door (6061-T6)	Single Wall Chamber ASME Section VIII, Div. I certified Stainless steel (316L) chamber and aluminum door (6061-T6)
Shelves / Trays	Stainless Steel wire tray	Aluminum tray
Steam Source	Internal chamber boiler via partitioned section	Internal chamber boiler via partitioned section
Steam Generation Mechanism	Electric resistive heaters submerged in chamber boiler	Electric resistive heaters submerged in chamber boiler
Drying Process	External air pulled through 0.3-micron HEPA filter then heated by internal cartridge heaters and external chamber wall heater for drying	External air pulled through 0.3-micron HEPA filter then heated by internal cartridge heaters for drying

Performance and/or Safety Characteristic	New Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 K243801	Predicate Device Fort Defiance Industries FRONT-LINE Field Sterilizer Model FL135 (K213457)
Control Technology	Electronic controller touch screen (PLC)	Electronic controller touch screen (PLC)
Process Monitors	Chamber pressure transmitter. Dual element chamber temperature sensor.	Chamber pressure transmitter. Dual element chamber temperature sensor.
Door Failsafe	Automatic Door Interlock	Automatic Door Interlock
Primary Overtemp and Overpressure Control	PLC Controller - Utilizing RTDs and Pressure Transmitter	PLC Controller - Utilizing RTDs and Pressure Transmitter
Secondary Overtemp Control	Thermocouple Temperature Cut-off Switch (TCO)	Thermocouple Temperature Cut-off Switch (TCO)
Secondary Overpressure Control	ASME Pressure Safety Valve	ASME Pressure Safety Valve
Electrical Input	120VAC ± 10%, 1Φ, 50/60 Hz, 15 A 230-240VAC ± 10%, 1Φ, 50/60 Hz, 15 A	120VAC ± 10%, 1Φ, 50/60 Hz, 15 A 230-240VAC ± 10%, 1Φ, 50/60 Hz, 15 A

8. Summary of Non-Clinical Testing

Fort Defiance Industries conducted validation studies in accordance with AAMI/ANSI ST55:2016 (FDA Recognition Number 14-518). Design outputs and testing demonstrate that the FRONT-LINE Model FL135 sterilizer meets all requirements of the standard.

Performance effectiveness of the sterilizer cycles and exposure time recommendations were demonstrated by the overkill method by passing 3 successive cycles at half the programmed exposure time to guarantee a sterility assurance level (SAL) of at least 10^{-6} probability of survival. Fort Defiance Industries validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical Instrumentation (AAMI). The Fort Defiance Industries FLl35 Sterilizer has been validated to meet the requirements of ANSI/AAMI ST55:2016, *Tabletop Steam Sterilizers* (FDA Recognition Number 14-518). Table 2 summarizes the FL135 effectiveness testing and results performed by Fort Defiance Industries.

Table 2: Performance Testing Summary

Test Procedure	AAMI ST55:2016 Requirements	AAMI ST55:2016 Tests	Measured Performance
Sterilizer Temperature Control & Pressure Measurement TP-5070	4.4.3 -0/+6°F temp control	5.4.3 - Temperature instrumented chamber tests to confirm steady state temperature control range and documentation of cold point	PASS
Software Verification and Validation TP-5110: Sterilizer Fault Conditions TP-5120: General Functions TP-5130: Full Cycle Verification	4.4.7 Sterilizer fault conditions	5.4.7 - Verified by inspection	PASS
Biological Performance – Wrapped Instrument TP-5160	4.5 Biological performance of sterilizers	5.5.4 Biological performance with wrapped instruments	PASS
Moisture Retention – Textiles TP-5190	4.7 Moisture Retention	5.7.1 Textile test packs	PASS
Moisture Retention – Wrapped Instrument TP-5200	4.7 Moisture Retention	5.7.2 Wrapped Instr. Test trays	PASS
Moisture Retention – Pouches TP-5210	4.7 Moisture Retention	5.7.3 Paper-plastic peel pouches	PASS

9. Safety

The Fort Defiance FRONT-LINE Field Sterilizer FL135 has been designed, constructed, and tested to meet the safety and performance requirements of various national safety codes and standards. The device complies with the following standards:

- ANSI/AAMI ST55:2016, *Tabletop Steam Sterilizers* (FDA Recognition Number 14-518).
- IEC 61010-1 Edition 3.1 2017-01, "*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1 General Requirements".* (FDA Recognition Number 19-34)
- IEC 61326-1:2020, "*Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements – Part 1: General Requirements"* (General Use)
- IEC 61010-2-040:2020, *"Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-disinfectors used to Treat Medical Materials"* (General Use)
- ASME Boiler and Pressure Vessel Code, Section VIII, Division I, 2023 Edition, Rules for Construction of Pressure Vessels (General Use)

Table 3 summarizes FRONT-LINE Field Sterilizer FL135 safety testing results performed by Fort Defiance Industries or a Third Party where indicated.

Table 3: Safety Testing Summary

FDI Test Procedure or 3rd Party	Standard	Tests	Measured Performance
3rd Party Testing Electrical Safety	IEC 61010-1 Edition 3.1 2017-01	3rd Party test protocol	PASS
3rd Party Testing EMC/EMI	IEC 61326-1:2020	3rd Party test protocol	PASS

10. Conclusion

The conclusion drawn from the nonclinical test results demonstrates that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device, K213457, Class II (21 CFR 880.6880, Product code FLE).