March 2, 2022

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

Re: K213457
Trade/Device Name: Fort Defiance Industries FRONT-LINE Field Sterilizer FL120,
Fort Defiance Industries FRONT-LINE Field Sterilizer FL135
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: October 26, 2021
Received: October 27, 2021

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 (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, PhD
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213457

Device Name
Fort Defiance Industries FRONT-LINE Field Sterilizer FL120,
Fort Defiance Industries FRONT-LINE Field Sterilizer FL135

Indications for Use *(Describe)*
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.

MODEL	CYCLE	MAXIMUM LOAD	EXPOSURE TEMP (F/C)*	EXPOSURE TIME (MIN)	NUMBER OF DYNAMIC AIR REMOVAL PULSES	DRY TIME (MINUTES)
FL120	IMMEDIATE USE (IUSS)	20 lbs.	270 / 132	4	3	0
			275 / 135	3	3	0
FL120	TEXTILES	3 TEXTILE PACKS **	250 / 121	30	3	60
			270 / 132	4	3	60
			275 / 135	3	3	60
FL120	WRAPPED INSTRUMENTS / POUCHES	20 lbs.	250 / 121	30	3	60
			270 / 132	4	3	60
			275 / 135	3	3	60
FL120	HANDPIECES	12 HANDPIECES	270 / 132	4	5	60
			275 / 135	3	5	60
FL135	IMMEDIATE USE (IUSS)	25 lbs	270 /132	4	3	0
			275 / 135	3	3	0
FL135	TEXTILES	3 TEXTILE PACKS **	250 / 121	30	3	60
			270 / 132	4	3	60
			275 / 135	3	3	60
FL135	WRAPPED INSTRUMENTS / POUCHES	25 lbs	250 / 121	30	3	60
			270 / 132	4	3	60
			275 / 135	3	3	60
FL135	HANDPIECES	12 HANDPIECES	270 / 132	4	5	60
			275 / 135	3	5	60

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
FL120 & FL135
K213457

Submitter / 510(k) Owner:
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Fort Defiance Industries LLC
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Fax: (866) 732-8086

Submission Date: March 2nd, 2022

1. Device Name

Trade Name:	Fort Defiance Industries FRONT-LINE Field Sterilizer FL120, Fort Defiance Industries FRONT-LINE Field Sterilizer FL135
Model Name(s):	FL120 / 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

K111736, Tuttnauer EZ11 Plus Electronic Tabletop Autoclave, product code FLE, cleared December 8, 2011

3. Description of Device

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 devices use electrical resistive heaters to produce steam as the sterilizing agent. The devices adhere 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 devices are 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 closed and does not permit the door to be opened until the internal chamber pressure is at atmospheric pressure. Additional safety features include electronic overtemperature and overpressure protection, an independent high temperature cutoff switch, and a pressure safety relief valve for the pressure vessel.

Only United States Food and Drug Administration cleared sterilization accessories should be used with these autoclaves.

4. Design and Materials

The FRONT-LINE Field Sterilizers, models FL120 and FL135, are steam sterilizers 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 devices are electronically controlled, and each device 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 series of autoclaves are steam sterilizers composed of a pressure vessel that utilizes electric resistive heaters to produce the sterilizing agent, steam, from a chamber boiler. The autoclaves contain an electronic control system that automatically initiates programmed Steam Flush Pressure Pulse (SFPP) phases to purge atmospheric air from the chamber followed by a timed steam exposure and drying phase. 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 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.

Model	Cycle	Maximum Load	Exposure Temperature[1] (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
FL120	Immediate Use (IUSS)	20 lbs.	270/132	4	0
			275/135	3	
	Textiles	3 Textile Packs[2]	250/121	30	60
			270/132	4	
			275/135	3	
	Wrapped Instruments / Pouches	20 lbs.	250/121	30	60
			270/132	4	
			275/135	3	
	Handpieces	12 Handpieces	270/132	4	60
			275/135	3	
FL135	Immediate Use (IUSS)	25 lbs.	270/132	4	0
			275/135	3	
	Textiles	3 Textile Packs[2]	250/121	30	60
			270/132	4	
			275/135	3	
	Wrapped Instruments / Pouches	25 lbs.	250/121	30	60
			270/132	4	
			275/135	3	
	Handpieces	12 Handpieces	270/132	4	60
			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 Sterilizers FL120 and 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 FRONT-LINE series sterilizers 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 FRONT-LINE series and the predicate with regards to chamber size, cycle parameters, and configuration of steam generation. The differences do not affect safety or effectiveness of the new devices compared to the predicate. Table 1 provides a summary of performance and safety characteristics of the proposed new devices and the predicate.

Table 1: Comparison of Technology

Performance and/or Safety Characteristic	**New Device Fort Defiance Industries FRONT-LINE Field Sterilizers FL120 & FL135 K213457**	**Predicate Device Electronic Tabletop Autoclave Tuttnauer EZ11 Plus K111736**
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 EZ Plus series of autoclaves are autoclaves designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow (e.g. dental handpieces, suction pipes) in ophthalmic, dental, and medical clinics; in first aid rooms; and in small laboratories.
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 IEC 61010-1 IEC 61326-1 IEC 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 Sterilizers FL120 & FL135 K213457	Predicate Device Electronic Tabletop Autoclave Tuttnauer EZ11 Plus K111736
Sterilization Cycles	Factory Pre-Programmed Steam Flush Pressure Pulse (SFPP) Conditioning Phase 30 min exposure @ 250°F 60 min dry time - Default 4 min exposure @ 270°F 60 min dry time - Default 3 min exposure @ 275°F 60 min dry time - Default	Factory Pre-Programmed Steam Flush Pressure Pulse (SFPP) Conditioning Phase 30 min exposure @ 250°F 1 min dry time - Default 3 or 4 min exposure @ 270°F Dry time dependent on load
Chamber Size & Volume	**FL120** 12” dia. X 23” lg. 1.6 cf. (45.3 L) **FL135** 13.5” dia. X 24” lg. 2.00 cf. (56.35 L)	11” dia. x 19.8” lg. 1.0 cf. (28.5 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 stainless-steel door
Shelves / Trays	Hard anodized aluminum shelf	Stainless Steel wire trays
Steam Source	Internal chamber boiler via partitioned section	Internal chamber boiler along length of chamber
Steam Generation Mechanism	Electric resistive heaters submerged in chamber boiler	External chamber wall electric band heaters
Dying Process	External air pulled through 0.3-micron HEPA filter then heated for drying	External air pulled through 0.2-micorn HEPA filter then heated for drying
Control Technology	Electronic controller touch screen (PLC)	Electronic controller touch screen (PLC)

Performance and/or Safety Characteristic	New Device Fort Defiance Industries FRONT-LINE Field Sterilizers FL120 & FL135	Predicate Device Electronic Tabletop Autoclave Tuttnauer EZ11 Plus K111736
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)	Capillary Temperature Cut-off Switch (TCO)
Secondary Overpressure Control	ASME Pressure Safety Valve	ASME Pressure Safety Valve
Electrical Input	120VAC +/- 10%, 1Ø, 50/60 Hz, 15 A 230-240VAC +/- 10%, 1Ø, 50/60 Hz, 15 A	120VAC +/- 5%, 60 Hz

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 Models FL120 and FL135 autoclaves meet all aspects 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 FRONT-LINE Field Sterilizers FL120 and FLl35 have been validated to meet the requirements of ANSI/AAMI ST55:2016, *Tabletop Steam Sterilizers* (FDA Recognition Number 14-518). Table 2 summarizes FRONT-LINE Field Sterilizer FL120 and 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 **Note:** TR-5072 reports Sterilizer Resolutions of Temperature Measurement TR-5075 reports Sterilizer Pressure Measurement TR-5077 reports Cold Point Relationship	4.4.2.1 Temperature monitoring 4.4.2.2 Relationship between RTD and chamber cold point 4.4.2.4 Temperature graduations of 1°C or less 4.4.3 -0/+6°F temp control 4.4.5.1 Pressure gauge of +/- 3% of full scale, resolution of 1 PSIG or less	5.4.2.1 - Verified by inspection 5.4.2.2 - Verified by inspection and test 5.4.3 5.4.2.4 - Verified by inspection 5.4.3 - Temperature instrumented chamber tests to confirm steady state temperature control range and documentation of cold point 5.4.5.1 - Verified by inspection and by testing against certified standards	PASS
Temperature Accuracy TP-5240	4.4.2.3 temperature accuracy of +/- 1°C over designated range	5.4.2.3 - Verified by testing against calibrated standards	PASS
Air Removal TP-5080	4.6.1 Air removal for dynamic air removal sterilizers	A.4.6.1 - Alternate test for Steam Flush Pressure Pulse Sterilizers	PASS
Software Verification and Validation TP-5100: Sterilizer Log Verification TP-5110: Sterilizer Fault Conditions TP-5120: General Functions TP-5130: Full Cycle Verification	4.4.7 Sterilizer fault conditions 4.4.8 Cycle documentation	5.4.7 - Verified by inspection 5.4.8 - Verified by inspection	PASS
Biological Performance – Textiles TP-5141	4.5 Biological performance of sterilizers	5.5.2 Biological performance with a textile pack	PASS
Biological Performance – Wrapped Instrument TP-5160	4.5 Biological performance of sterilizers	5.5.4 Biological performance with wrapped instruments	PASS
Biological Performance – Dental Handpieces TP-5170	4.5 Biological performance of sterilizers	5.5.5 Biological performance with dental handpieces	PASS

Test Procedure	AAMI ST55:2016 Requirements	AAMI ST55:2016 Tests	Measured Performance
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 Drying Test TP-5210	4.7 Moisture Retention	5.7.3 Paper-plastic peel pouches	PASS
Endotoxin and Water Quality TP-5220	A.4.2.6 Water supply reservoir	A.4.2.6 Water supply reservoir	PASS

9. Safety

The Fort Defiance FRONT-LINE Field Steam Sterilizers have 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, 2019 Edition, Rules for Construction of Pressure Vessels (General Use)

Table 3 summarizes FRONT-LINE Field Sterilizer FL120 and 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
Labeling TP-5010 (FDI)	AAMI ST55:2016 - 4.1.1 Device Markings AAMI ST55:2016 - 4.1.2 Information Manual AAMI ST55:2016 - 4.1.3 Service Manual	AAMI ST55:2016 - 5.1 Visual inspection only	PASS
Sterilizer Safety TP-5050 (FDI)	AAMI ST55:2016 - 4.3.1 Interlock AAMI ST55:2016 - 4.3.2 Thermal hazards AAMI ST55:2016 - 4.3.3 Aborting cycles	AAMI ST55:2016 - 5.3.1 Interlock functions under conditions described AAMI ST55:2016 - 5.3.2 Thermal hazard testing per UL-61010 AAMI ST55:2016 - 5.3.3 Verified by inspection	PASS
General Inspection TP-5060 (FDI)	4.2.1 & 4.2.2 Pressure vessel requirements 4.2.4 Corrosion resistance 4.2.5 Air filters 4.2.6 Water supply reservoir 4.4.4 Sterilizer exposure timer 4.4.6 Cycle completion	AAMI ST55:2016 - 5.2.1 Verified by compliance to ASME BPVC Section VIII Division 1 Code, requirements in UL 61010-1 and IEC 61010-2-040 AAMI ST55:2016 - 5.2.4 Material corrosion resistance review AAMI ST55:2016 - 5.2.5 Air filter inspection necessary filtration efficiency and filter readily accessible AAMI ST55:2016 - 5.2.6 Verified by inspection AAMI ST55:2016 - 5.4.4 Verified by inspection and timer testing to NIST standard AAMI ST55:2016 - 5.6.6 Verified by inspection	PASS
3rd Party Testing Electrical Safety	IEC 61010-1 Edition 3.1 2017-01	3rd Party test protocol	PASS
3rd Party Testing Electrical/Sterilizer Specific Safety	IEC 61010-2-040:2020	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 testing demonstrates that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device, K111736, Class II (21 CFR 880.6880, Product code FLE).