DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2014

Fort Defiance Industries, Inc.
Mr. Chris Yerger
President
155 B Natalie Boulevard
Loudon, TN 37774

Re: K141009
Trade/Device Name: Fort Defiance Automated Steam Sterilizer Model P2131
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: November 18, 2014
Received: November 18, 2014

Dear Mr. Yerger:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141009

Device Name
Automated Field Steam Sterilizer Model P2131

Indications for Use *(Describe)*

The Fort Defiance Industries, Inc. Automated Field Steam Sterilizer Model P2131 is designed for sterilization of porous and non-porous, heat- and moisture-stable materials (e.g., surgical instruments and textiles) used in healthcare facilities. The P2131 sterilizer is a transportable device designed for field use in a variety of austere environments.

Cycle	Recommended Use	Maximum Load	Exposure Temperature (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
Immediate Use (IUSS)	Unwrapped nonporous (e.g., instruments) and porous items in mixed loads	36 lbs.	270/132	4	0
Textiles	Textile packs	3 textile packs*	270/132	4	5**
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	4	20**
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	10	20**
Bowie-Dick Test	Test	NA	273/134	3.5	0
Vacuum Leak Test	Test	NA	NA	Test time: 20	0

Notes:
* AAMI standard 16-towel pack (9"x9"x6")
** Dry times default to established standard conditions, but can be manually increased.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(K141009)
For
Automated Field Steam Sterilizer
Model P2131

Fort Defiance Industries, Inc.
155 B Natalie Blvd
Loudon, TN 37774
Phone: (865) 408-0100
Fax No: (865) 408-0960

Chris Yerger
President
Fort Defiance Industries, Inc.
Phone: 865-408-0100
Fax: 865-408-0960

Submission Date: April 15, 2014

1. **Device Name**

Trade Name:	Automated Field Steam Sterilizer
Model Name:	P2131
Common/usual Name:	Steam Sterilizer
Classification Name:	Steam Sterilizer (21 CFR 880.6880) Product Code FLE

2. **Predicate Device**

K030789, Amsco Century Steam Sterilizer, product code [FLE] cleared March 26, 2003

3. **Description of Device**

The Fort Defiance Industries, Inc. model P2131 sterilizer is an automated steam sterilizer designed for sterilization of porous and non-porous, heat- and moisture-stable materials (e.g., surgical instruments and textiles) used in healthcare facilities. The P2131 sterilizer is a transportable device designed for field use in a variety of austere environments.

The P2131 is a pre-vacuum and post-vacuum sterilizer that has a conditioning stage with vacuum air removal before the start of the exposure stage, as well as a post-exposure drying stage that is based on the combined operation of heat plus vacuum. The sterilization agent is steam that is electrically-generated in a jacketed boiler.

The P2131 sterilizer consists of three components that work together as one integrated system. These components are the (1) Sterilizer, (2) Water Recovery System (WRS), and (3) the Sterilizer Water Softener (SWS). The WRS reclaims hot condensate and exhaust steam for re-use by the sterilizer. The WRS also includes a water eductor, which provides the vacuum capability for the pre and post-vac phases of sterilization. The Sterilizer Water Softener (SWS) filters and de-mineralizes the incoming water to prevent scale build-up.

The P2131 is an automated, microprocessor-controlled, prevacuum autoclave. It has a fully-jacketed, horizontal-type pressure vessel. The P2131 is of welded aluminum alloy construction to minimize weight. The chamber assembly, with internal dimensions of 16″ diameter x 36″ long, is supported in a combination frame and endcap assembly to provide rigidity and protection. These endcaps, when closed, completely enclose and protect the sterilizer and its heat source providing the capability to serve as a shipping container. When the endcaps are opened they provide an integral stand, placing the sterilizing chamber and operating controls at a convenient working height.

4. **Intended Use**

The Fort Defiance Industries, Inc. Automated Field Steam Sterilizer Model P2131 is designed for sterilization of porous and non-porous, heat- and moisture-stable materials (e.g., surgical instruments and textiles) used in healthcare facilities. The P2131 sterilizer is a transportable device designed for field use in a variety of austere environments.

The Fort Defiance Automated Field Steam Sterilizer is equipped with the following factory-validated preprogrammed sterilization cycles:

Cycle	Recommended Use	Max Load	Exposure Temperature (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
Immediate Use (IUSS)	Unwrapped nonporous (e.g., instruments) and porous items in mixed loads	36 lbs.	270/132	4	0
Textiles	Textile packs	3 textile packs[1]	270/132	4	5[2]
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	4	20[2]
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	10	20[2]
Bowie-Dick Test	Test	NA	273/134	3.5	0
Vacuum Leak Test	Test	NA	NA	Test time 20	0

[1] AAMI standard 16-towel pack (9”x9”x6”).
[2] Dry times default to established standard conditions, but can be manually increased.

5. **Substantial Equivalence**

The previously cleared device and the P2131 Sterilizer are both traditional pre-vacuum steam sterilizers of similar chamber size using 4 and 10 minute 270°F cycles with the same Intended Use. Both sterilizers use electric heaters to generate steam, water eductors for vacuum, and electronic controllers with touch screens for cycle control. The main difference between the devices is that the P2131 is a transportable device so it uses light-weight aluminum for the frame, jacket and chamber instead of stainless steel for the chamber and carbon steel for the boiler. This provides some new technological differences from the predicate, but the differences do not affect the safety or effectiveness of the device. The table below provides a summary of the proposed new device and predicate device technological characteristics.

Technological Characteristic	**New Device Fort Defiance Industries Automated Field Steam Sterilizer**	**Predicate Device STERIS AMSCO Century Steam Sterilizer**
Intended Use	A steam sterilizer designed for sterilization of porous and non-porous, heat- and moisture-stable materials (e.g., surgical instruments and textiles) in healthcare facilities. The P2131 sterilizer is a transportable device designed for field use in a variety of austere environments.	A steam sterilizer designed for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.
Operating Principle	Steam is the sterilization agent. Traditional.	Steam is the sterilization agent. Traditional.
Sterilization Cycles	Factory Pre-Programmed Prevac 4/0 @ 270°F Prevac 4/5 @ 270°F Prevac 4/20 @ 270°F Prevac 10/20 @ 270°F Bowie-Dick & Vacuum Leak tests	Factory Pre-Programmed Prevac 3/1 @ 270°F Prevac 10/1 @ 270°F Prevac 4/3 @ 270°F Prevac 4/20 @ 270°F Prevac 3/16 @ 275°F 4 Gravity cycles Bowie-Dick & Vacuum Leak tests
Chamber Size & Volume	16” dia. x 36” lg. 4.2 cf. (118.6 L)	16” x 16” x 26” 3.9 cf. (108.7 L)
Design	Steam-jacketed	Steam-jacketed
Chamber	ASME Section VIII, Div. I certified Aluminum chamber, door, trays, frame and boiler (Aluminum for lighter weight)	ASME Section VIII, Div. I certified Stainless steel chamber, door, trays and frame. Carbon steel boiler.
Steam Source	Integrated steam boiler.	Integrated steam boiler or optional house steam.

Technological Characteristic	New Device Fort Defiance Industries Automated Field Steam Sterilizer	Predicate Device STERIS AMSCO Century Steam Sterilizer
Steam Generation	Electric heaters	Electric heaters
Vacuum System	Water eductor	Water eductor
Control Technology	Electronic controller Touch Screen	Electronic controller Touch Screen
Process Monitors	Chamber pressure transmitter. Dual element chamber drain temperature sensor.	Chamber pressure transmitter. Dual element chamber drain temperature sensor.
Safety Pressure Relief Valves	ASME approved	ASME approved
Electrical (Controls)	120V, 1Ø, 50/60 Hz	120V, 1Ø, 50/60 Hz
Electrical (Boiler)	208V, 3Ø, 50/60Hz, 30A	208V, 3Ø, 50/60Hz, 83A 240V, 3Ø, 50/60Hz, 72A 480V, 3Ø, 50/60Hz, 37A

6. **Effectiveness**

Effectiveness of sterilizer function and exposure time recommendations was demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} probability of survival. Fort Defiance 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 Automated Field Steam Sterilizer has been validated to meet the requirements of ANSI/AAMI ST8:2013, *Hospital Steam Sterilizers.*

7. **Safety**

The Fort Defiance Automated Field Steam Sterilizer Model P2131 has been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Model P2131 sterilizer will comply with the following requirements:

- UL 61010-1 2nd Edition, "*Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1 General Requirements".*

- IEC 61010-2-040 1st Edition, *"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"*

- ASME Boiler and Pressure Vessel Code, Section VIII, Division I, 2013 Edition, Rules for Construction of Pressure Vessels

8, Hazards – Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

The technology designed into the Fort Defiance Automated Field Steam Sterilizer provides control safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

9. Conclusion

The Fort Defiance Industries Automated Field Steam Sterilizer Model P2131 has been validated to meet the requirements of ANSI/AAMI ST8:2013. The results of the Automated Field Steam Sterilizer validation studies demonstrate that the sterilizer performs as intended. Based on the information provided in this premarket notification, it can be concluded that the Automated Field Steam Sterilizer Model P2131 is substantially equivalent to the predicate device and is as safe and as effective when used as intended.