Alternative Pioneering Research and Development
Revolutionary Science
Isaac Erickson
Chief Technology Officer
17319 Lake Blvd
Shafer, Minnesota 55074

Re: K180272
Trade/Device Name: Saniclave 250
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: June 22, 2018
Received: June 29, 2018

Dear Isaac Erickson:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180272

Device Name

Saniclave 250

Indications for Use *(Describe)*

The Revolutionary Science Saniclave 250 is designed to be used in medical and dental clinics, hospitals and other facilities where reusable sterile equipment is used. It is intended to sterilize wrapped and unwrapped heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars (lumens greater than 3mm inner diameter and less than 70mm in length, excluding dental handpieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.

The Saniclave 250 has 3 factory-programmed cycles:

Cycle	Sterilization Temperature	Sterilize Time	Dry Time	Recommended Load
Gravity, small load, wrapped*	121°C	30 minutes	30 minutes	**1 tray, wrapped* instruments, maximum weight 4.5 lbs** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars
Gravity, small load, unwrapped*	121°C	30 minutes	N/A	**1 tray, unwrapped* instruments, maximum weight 4.5 lbs** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars
Gravity, large load, unwrapped*	121°C	30 minutes	N/A	**3 trays, unwrapped* loaded evenly, maximum weight 8.0 lbs** Heat and moisture stable solid instruments, lumened devices and trocars only

**A wrapped load is wrapped or pouched in autoclave packaging that is FDA cleared for 30 min at 121°C. An unwrapped load is not wrapped or pouched and is intended for immediate use.*

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.

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

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510(k) Summary

Submitted by: Alternative Pioneering Research and Development
Revolutionary Science
17319 Lake Blvd.
Shafer, MN 55074

Contact Person: Isaac Erickson, Chief Technology Officer
651-353-7806

Date: 23 July 2018

Device Name: Saniclave 250 (RS-SC-250)
Model Number: RS-SC-250

Common Name: Steam Sterilizer

Classification: Steam Sterilizer (21 C.F.R. § 880.6880)
Class II Device Product Code: FLE

Predicate Device: The Revolutionary Science Saniclave 250 (RS-SC-250) is claimed to be substantially equivalent to the FDA cleared Saniclave 200 under the 510(k) number K112811.

Technical Characteristics, Intended Use, and cycle parameters are all similar to the predicate device.

Intended Use:

The Revolutionary Science Saniclave 250 is designed to be used in medical and dental clinics, hospitals and other facilities where reusable sterile equipment is used. It is intended to sterilize wrapped and unwrapped heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars (lumens greater than 3mm inner diameter and less than 70mm in length, excluding dental handpieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.

The Saniclave 250 has 3 factory-programmed cycles:

Cycle	Sterilization Temperature	Sterilize Time	Dry Time	Recommended Load
Gravity, small load, wrapped*	121°C	30 minutes	30 minutes	**1 tray, wrapped* instruments, maximum weight 4.5 lbs** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars
Gravity, small load, unwrapped*	121°C	30 minutes	N/A	**1 tray, unwrapped* instruments, maximum weight 4.5 lbs** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars
Gravity, large load, unwrapped*	121°C	30 minutes	N/A	**3 trays, unwrapped* loaded evenly, maximum weight 8.0 lbs** Heat and moisture stable solid instruments, lumened devices and trocars only

**A wrapped load is wrapped or pouched in autoclave packaging that is FDA cleared for 30 min at 121°C. An unwrapped*

load is not wrapped or pouched and is intended for immediate use.

Device Description: The Saniclave 250 by Revolutionary Science (model number RS-SC-250) is a 120 volt front loading autoclave.

Explanation of how the device functions: The Saniclave works like most other table top steam sterilizers by boiling water in a pressurized vessel (or chamber). As the water boils, the chamber pressurizes and the steam sterilizes the instruments placed inside.

Scientific concepts that form the basis for the device: The Saniclave technology is based on the scientific concept that prolonged saturated pressurized steam at or over a temperature of 121degrees Celsius kills bacteria.

Significant physical performance characteristics:

Device design:
Material used: The following materials were used in the construction of the Saniclave:
Chamber (including door): Draw formed stainless steel
Exterior enclosure: ABS thermoformed plastic
Base plate: Galvanized steel
Seal: Injection molded silicone
Plumbing: extruded silicone tubing
Solenoid valve: Cast brass and plastic
Heater: Tubular heating element, nichrome wire and Incoloy sheathe.
Circuit board with surface mount electronics
This device has no direct or indirect patient contact.

Basic physical properties: The single heating element (permantently affixed to the bottom inside the chamber with bulkhead fittings) generates all heat for the autoclave, including preheat, sterilization and dry modes. It is immersed in the water of the chamber. When the cycle is initiated, the heater turns on and boils the water.

Outside dimensions: 16”x13.5”x21”
Internal chamber dimensions (including door): 9” diameter x 10.5” deep

Comparison to Predicate Device:

The Saniclave 250 employs the same materials in construction as the Saniclave 200. It has the same factory-programmed cycle parameters. The only two significant differences between these two machines are: 1. A large unwrapped cycle has been added to accommodate 3 trays and 8lbs of trocars, lumened devices and solid instruments evenly distributed among the trays. This cycle is initiated with the same button as the smaller 4.5 lbs unwrapped cycle but has been tested with the larger load. 2. Lumened devices of 3mm inner diameter and 70mm in length are claimed in the indications for use.

These differences do not raise new questions for safety or effectiveness. The additional weight and trocars were tested and support a 10^{-6} SAL for the full sterilization cycle following the gravity steam sterilization half-cycle of 121 degrees C for 15 minutes.

Technological Characteristics Comparison Table

Description	K112811 200 Saniclave	K180272 250 Saniclave	Comparison
Indications for Use	The Revolutionary Science Saniclave 200 is designed to be used in medical and dental clinics, hospitals and other facilities where reusable sterile equipment is used. It is intended to sterilize wrapped and unwrapped heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, (excluding lumened devices and dental handpieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.	The Revolutionary Science Saniclave 250 is designed to be used in medical and dental clinics, hospitals and other facilities where reusable sterile equipment is used. It is intended to sterilize wrapped and unwrapped heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars (lumens greater than 3mm inner diameter and less than 70mm in length, excluding dental handpieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.	Similar
Chamber Size	9” diameter x 10.5” deep (including door)	9” diameter x 10.5” deep (including door)	Same
Sterilization cycles	Gravity, small load, wrapped: 121°C for 30 minutes with 30 minutes of dry time. **1 tray, wrapped instruments, maximum weight 4.5 lbs:** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, excluding lumened devices and dental hand pieces. Gravity, small load, unwrapped: 121°C for 30 minutes with no dry time. **1 tray, unwrapped instruments, maximum weight 4.5 lbs:** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, excluding lumened devices and dental hand pieces.	Gravity, small load, wrapped: 121°C for 30 minutes with 30 minutes of dry time. **1 tray, wrapped instruments, maximum weight 4.5 lbs:** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars Gravity, small load, unwrapped: 121°C for 30 minutes with no dry time. **1 tray, unwrapped instruments, maximum weight 4.5 lbs:** Heat and moisture stable solid instruments, mated surfaces, knurled, hinged devices, including lumened devices and trocars Gravity, large load, unwrapped: 121°C for 30 minutes with no dry time. **3 trays, unwrapped loaded evenly, maximum weight 8.0 lbs:** Heat and moisture stable solid instruments, lumened devices and trocars only	Different
Materials used in the sterilizer	Chamber (including door): Draw formed stainless steel (316 grade) Exterior enclosure: ABS thermoformed plastic	Chamber (including door): Draw formed stainless steel (316 grade) Exterior enclosure: ABS thermoformed plastic	Same

	Base plate: Galvanized steel Seal: Injection molded silicone Plumbing: extruded silicone tubing Solenoid valve: Cast brass and plastic Heater: Tubular heating element, nichrome wire and Incoloy sheathe. Circuit board with surface mount electronics	Base plate: Galvanized steel Seal: Injection molded silicone Plumbing: extruded silicone tubing Solenoid valve: Cast brass and plastic Heater: Tubular heating element, nichrome wire and Incoloy sheathe. Circuit board with surface mount electronics	
Built according to standard	ANSI/AAMI ST55	ANSI/AAMI ST55	Same
Physical Testing	Parametric testing of temperature (121 °C for 30 min) and pressure (15 psi)	Parametric testing of temperature (121 °C for 30 min) and pressure (15 psi)	Same
Biological Testing	Sterilization validation with worst case load	Sterilization validation with worst case load, including lumened devices	Similar
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Biocompatibility	No patient contacting components	No patient contacting components	Same
EMC and Electrical Safety	EMC and Electrical Safety Compliance to EN 61010-2-040, EN 61010-1, EN 60601-1-2, EN 60601-1-1, EN 60601-1	EMC and Electrical Safety Compliance to EN 61010-2-040, EN 61010-1, EN 60601-1-2, EN 60601-1-1, EN 60601-1	Same
Electrically generated steam	Yes	Yes	Same
Multiple Safety features	Yes	Yes	Same
Spring loaded safety release valve	Yes	Yes	Same
Digital display	Yes	Yes	Same
Optional printer	Yes	Yes	Same
Plastic enclosure	Yes	Yes	Same
120 VAC input	Yes	Yes	Same

* Substantial Equivalence of the new claims are discussed below.

Non-Clinical Testing:

Physical and biological testing were performed in accordance with ANSI/AAMI ST55:2016. Testing showed that Saniclave 250 meets all applicable requirements of this standard. Physical testing measured pressure and temperature inside the chamber in an empty and fully loaded state. Five precalibrated temperature sensors were placed inside the chamber measuring temperature in the front, back, upper, lower, and middle of the chamber so as to provide a good understanding of the temperature distribution in the chamber. One precalibrated pressure

transducer was used to monitor pressure. Temperature and pressure was found to be within operating parameters. A loaded test with one tray and 4.5 lbs was performed with instruments (including hinged and knurled devices but not lumens) and inoculated with *G. Bacillus Stearothermophilus* in an artificial soil so as to present the greatest challenge to sterilization. A cycle was run and the inoculum tested. No growth was observed.

A separate test was also performed with the additional trocars (with lumens measuring 3mm inner diameter and 70mm in length) using 3 trays and 8.0 lbs inoculated with *G. Bacillus Stearothermophilus* in an artificial soil so as to present the greatest challenge to sterilization. A cycle was run and the inoculum tested. No growth was observed.

Electromagnetic Compatibility (EMC) and Safety Compliance: *The Saniclave 250 was tested to the following standards.*

EMC: EN 60601-1-2 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS

Safety: EN 60601-1-1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS

EN 60601-1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

EN 61010-2-040 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

EN 61010-1 SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE. GENERAL REQUIREMENTS

Clinical Data:
No clinical data was needed for this device. This device has no direct or indirect patient contact.

Conclusion:
Based on a comparison of technologies, indications for use, and process parameters the Saniclave 250 (RS-SC-250) is as safe, as effective, and performs as well or better than the legally marketed predicate device, Saniclave 200 (RS-SC-200), cleared under 510k number K112811.