510(k)Summary

MAY 2 3 2013

Submitted by: Revolutionary Science
17319 Lake Blvd.
Shafer, MN 55074

Contact Person: Isaac Erickson, Vice President
651-353-7806

Date: September, 24th, 2012

Device Name: Saniclave 102

Common Name: Autoclave

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

Predicate Device: Revolutionary Science claims substantial equivalence to the FDA cleared Revolutionary Science Saniclave 200 device cleared under the 510(k) number K112811.

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

Intended Use:

Indications For Use:

The Revolutionary Science Saniclave 102 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 unwrapped heat and moisture stable solid instruments, mated surfaces, knurled and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes. Unwrapped instruments that were sterilized should be used immediately after sterilization is completed (immediate use sterilization). The chamber must be manually drained and wiped dry after each cycle.

Outside dimensions: 14.5" (L), 13.5" (W), 12.5" (H)
Internal chamber dimensions (including door): 9" diameter x 8.25" deep
Chamber volume: 8 liters

Cycle Parameters

	Recommended Use	Maximum Load	Sterilization Temperature	Sterilization Time	Dry Time
Unwrapped	Instruments intended to be used immediately upon sterilization	4.5 lbs	121°C	30	0

Device Description: The Saniclave 102 by Revolutionary Science (model number RS-SC-102) is a 120 volt 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):	Drawformed 300 series stainless steel
Exterior enclosure:	Injection molded ABS
Base plate:	Galvanized steel
Seal:	Injection molded silicone
Heater:	Tubular heating element

Microprocessor based circuit board

Basic physical properties: The single heating element (affixed to the bottom of the chamber) generates all heat for the autoclave, including preheat and sterilization. When the cycle is initiated the heater turns on and boils the water.

Outside dimensions: 14.5" (L), 13.5" (W), 12.5" (H)
Internal chamber dimensions (including door): 9" diameter x 8.25" deep
Chamber volume: 8 liters

Cycle Parameters:

	Recommended Use	Maximum Load	Sterilization Temperature	Sterilization Time	Dry Time
Unwrapped	Instruments intended to be used immediately upon sterilization	4.5 lbs	121°C	30	0

Note-- This sterilizer has not been validated for wrapped instruments.

Non-Clinical Testing:
Physical and biological testing were performed in accordance with ANSI/AAMI ST55:2010.

Feature	**PredicateDevice: RevolutionaryScience Saniclave200(RS-SC-200)**	**RevolutionaryScience Saniclave102(RS-SC-102)**	**Justification**
FDA 510(K) number	K112811	K122978	
EPA registered component? Y/N	N	N	
Labeling/ Intended 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 and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.	The Revolutionary Science Saniclave 102 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 unwrapped heat and moisture stable solid instruments, mated surfaces, knurled and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes. Unwrapped instruments that were sterilized should be used immediately after sterilization is completed (immediate use sterilization). The chamber must be manually drained and wiped dry after each cycle. Outside dimensions: 14.5" (L), 13.5" (W), 12.5" (H) Internal chamber dimensions (including door): 9" diameter x 8.25" deep Chamber volume: 8 liters Cycle Parameters Unwrapped Recommended Use – Instruments intended to be used immediately upon sterilization Maximum load: 4.5 lbs Sterilization Temperature: 121C Sterilization time: 30 Dry time: 0	
Type	Gravity Displacement Steam Sterilizer	Gravity Displacement Steam Sterilizer	
Overall Size	16" (L), 13.5" (W), 21" (H)	14.5" (L), 13.5" (W), 12.5" (H)	

Internal Chamber Size Construction	9" diameter x 10.5" deep (including door) Draw formed 300 series stainless steel	9" diameter x 8.25" deep (including door) Draw formed 300 series stainless steel	
Door Construction	Draw formed 300 series stainless steel 9" diameter x 2.5" deep	Draw formed 300 series stainless steel 9" diameter x 0.25" deep	
Tray Size Construction	8.6"x 8.2" Stainless Steel	8" diameter (round) Stainless steel	
Heater	500 Watt	1250 Watt	The 1250 heater is on the underside of the chamber. For this reason a user can clean the inside of the chamber, since the heater is not visible. The predicate has a 500 watt internal heater. The chamber is a little more difficult to clean around this heater. Both heaters are CE approved for safety and serve the same purpose during preheat and sterilizing modes. The thermal profile testing results are similar for both the predicate and subject device.
Process Parameters Time Temperature Pressure	 30 minutes 121°C 15psi	 30 minutes 121°C 15psi	
Process Monitors: recorders, gauges, printouts	Pressure Gauge: Digital display indicates pressure Temperature Gauge: Digital display indicates current temperature, pressure and cycle time remaining in sterilization mode Printouts: prints process parameters including highest and lowest temperature achieved in sterilization mode (printer is optional)	Temperature: Digital display indicates current temperature (in degrees C) and cycle time remaining in sterilization mode	See below
Software/Firmware Controlled	Yes -Integrated chip controls time and temperature.	Yes -Integrated chip controls time and temperature.	
Cycle(s) Comparison	wrapped: 121°C for 30 min, plus 30 min dry mode unwrapped: 121°C for 30 min (no dry mode)	Unwrapped only: 121°C for 30 min	
Process Equivalent Time (F_0)	Greater than or equal to 30 minutes	Greater than or equal to 30 minutes	
Solenoid, plumbing and water exhaust tank.	These parts work in conjunction with each other to automatically drain the used water from the chamber at the end of the cycle. Dry mode is initiated after the chamber water is drained.	These parts are not employed on the subject device.	The reason that these parts are absent in the subject device is because 1. Water must be drained manually. The following statement is found on page N-17 on 014_Proposed Labeling "NEVER reuse water left in the chamber. Re-used water may contain endotoxins. Drain used water from the chamber and refill chamber with clean, distilled water before each cycle." 2. Only unwrapped instruments may be sterilized according to the intended use statement. Unwrapped instruments do not require a dry mode. 3. The FDA cleared Prestige 2100 autoclave (K962903) does not contain

			a means to expel the used water from the chamber. The user must manually drain the water after each cycle.
Pressure transducer	The predicate device has a pressure transducer. Pressure is recorded and displayed on the digital display/printout.	The subject device does not employ a pressure transducer.	The reason the pressure transducer is absent is because 1. Pressure is controlled mechanically: The ZPD valve lets cold air release until the temperature is sufficient to build pressure. Then the ZPD seals shut and the pressure builds. The Pressure Relief valve will release excess pressure if chamber pressure is too high (24psi). The temperature probe works in conjunction with the microprocessor to regulate the temperature of the chamber. 2. We require an FDA cleared class 5 integrator be used for each cycle. Class 5 integrators confirm that pressure, temperature and time were achieved. 3. The FDA cleared Prestige 2100 autoclave (K962903) does not contain a pressure transducer or pressure monitoring system.
Printer connection or storage device	The predicate has a printer connection in accordance to ST55. Memory for printout will only store one cycle until reset by the user. Only 'CC' or error mode is stored until it is reset by the user at cycle end.	The subject device does not contain a printer connection or printer. It does contain memory storage for one cycle. Only 'CC' or error mode is stored until it is reset by the user at cycle end.	The reason the printer connection is absent is because 1. It does contain memory storage for one cycle. Only 'CC' or error mode is stored until it is reset by the user at cycle end. 2. We provide a recommended Saniclave 102 Cycle Documentation Table on N-15 of 014_Proposed Labeling. 3. We require an FDA cleared class 5 integrator be used for each cycle. Class 5 integrators confirm that pressure, temperature and time were achieved. 4. The FDA cleared Prestige 2100 autoclave (K962903) and the Tuttnauer 1730M autoclave (K973550) do not contain a printer, printer connection or comprehensive data storage capability.

Conclusion:

Based on a comparison of technologies, indications for use, and process parameters Revolutionary Science finds that the Saniclave 102 (RS-SC-102) is substantially equivalent to the legally marketed Revolutionary Science Saniclave 200 device cleared under the 510(k) number K112811.

Revolutionary Science claims that the subject device is substantial equivalence to the FDA cleared Revolutionary Science Saniclave 200 device cleared under the 510(k) number K112811.

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

May 23, 2013

Alternative Pioneering Research and Development, Inc.
Mr. Isaac Erickson
Vice President
Revolutionary Science Division
17319 Lake Boulevard
SHAFER MN 55074

Re: K122978
Trade/Device Name: Saniclave 102
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: May 8, 2013
Received: May 14, 2013

Dear Mr. 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.

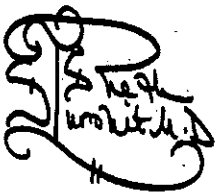
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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,



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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122978

Device Name: Saniclave 102

Indications For Use:

The Revolutionary Science Saniclave 102 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 unwrapped heat and moisture stable solid instruments, mated surfaces, knurled and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes. Unwrapped instruments that were sterilized should be used immediately after sterilization is completed (immediate use sterilization). The chamber must be manually drained and wiped dry after each cycle.

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Prescription Use _____ AND/OR Over-The-Counter Use ___x___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.05.22 17:36:41 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122978