

510(k) Summary

JAN 11 2012

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

Contact Person: Isaac Erickson, Vice President
651-373-7806

Date: 21 November 2011

Device Name: Saniclave 200 (RS-SC-200)

Common Name: Autoclave

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

Predicate Device: The Revolutionary Science Saniclave 200 (RS-SC-200) is claimed to be substantially equivalent to the FDA cleared B/T (Barnstead/Thermolyne) "Sterilemax" under the 510(k) number K953938.

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

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.

Device Description: The Saniclave 200 by Revolutionary Science (model number RS-SC-200) 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

Basic physical properties: The single heating element

(permanently 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

Cycle Parameters:

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

*Note-- This sterilizer has not been validated for double pouching.

Non-Clinical Testing:

Physical and biological testing were performed in accordance with ANSI/AAMI ST55:2010. Testing showed that Saniclave 200 meets all requirements of this standard.

Conclusion:

Revolutionary Science finds that the Saniclave 200 (RS-SC-200) is substantially equivalent to the legally marketed B/T (Barnstead/Thermolyne) "Sterilemax" cleared under the 510(k) number K953938.



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

Alternative Pioneering Research and Development
C/O Mr. Isaac Erickson
Vice President
Revolutionary Science
17319 Lake Boulevard
Shafer, Minnesota 55074

JAN 11 2012

Re: K112811
Trade/Device Name: Saniclave 200
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 21, 2011
Received: December 22, 2011

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.

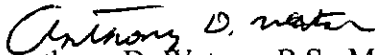
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,


Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K112811

510(k) Number (if known): unknown

Device Name: Saniclave 200

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 and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees Celsius for 30 minutes.

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)

Erin F. Clavico-Will
(Division Sign-Off)

Division of Anesthesiology, General Hospital
infection Control, Dental Devices

510(k) Number: K112811