JAN - 6 2014

Attachment 2

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K132439.

1. **Submitter's Identification:**

Sakura Seiki Co., Ltd.
46-1, Shinden
Chikuma, Nagano 387-0018
Japan
Phone: 81-26-273-3583
Fax: 81-26-273-2584

Date Summary Prepared: January 3, 2014

2. **Name of the Device:**

Proprietary name:
Sakura Steam Sterilizer ASSR-AO12
Sakura Steam Sterilizer ASSR-AO12W
Sakura Steam Sterilizer ASSR-AO12P
Sakura Steam Sterilizer ASSR-AO12PW
Skytron Integrity 270 Steam Sterilizer
Skytron Integrity 270 VP Steam Sterilizer

Common Name: Steam Sterilizer
Regulation: 21CFR Part 880.6880, Class II
Product Code: FLE

3. **Common or Usual Name:**

Common name: Steam Sterilizer
Classification name: Sterilizer, Steam

4. **Predicate Device Information:**

Skytron Integrity 215 Steam Sterilizer, Skytron Integrity 215 SG Steam Sterilizer, K120149

5. **Description:**

The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-

AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizer, are Class II, Product Code FLE Medical Devices as defined by CFR§880.6880 and defined for use in healthcare facilities.

The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizer provide efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizers also dry items that have been sterilized with wet steam.

6. Intended Use:

Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are available in the following configuration.

26.5" x 37.5" x 53" chamber size, Single or Double Door Prevacuum and Gravity
Sakura Steam Sterilizer ASSR-AO12 is a single door.
Sakura Steam Sterilizer ASSR-AO12W is a double door (pass through).
Sakura Steam Sterilizer ASSR-AO12P is a single door with vacuum pump.
Sakura Steam Sterilizer ASSR-AO12PW is a double door (pass through) with vacuum pump.
Skytron Integrity 270 Steam Sterilizer is a single or double door (pass through).
Skytron 270 VP Steam Sterilizer is a single or double door (pass through) with vacuum pump.

Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are equipped with the following factory-programmed sterilization cycle values. The following factory-programmed cycles are validated according to ANSI/AAMI ST8: 2008.

Cycle	Validated Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash 1 (IU 1)	One unwrapped, nonporous instrument no heavier than 0.22 lbs. (100 gram)	270 F (132 C)	3 minutes	1 minute
Flash 2 (IU 2)	Maximum of sixteen (16) unwrapped instrument	270 F (132 C)	4 minutes	1 minute

	trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.			
Prevacuum 270	Maximum of sixteen (16) double-wrapped instrument trays, maximum weight 25 pound (11.3kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	30 minutes
Prevacuum 275	Maximum of sixteen (16) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	275 F (135 C)	3 minutes	30 minutes
Express Prevacuum (IU 3)	Maximum of sixteen (16) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier.	270 F (132 C)	4 minutes	3 minutes
Gravity 1	Maximum of thirty-two (32) -fabric packs.	250 F (121 C)	30 minutes	15 minutes
Gravity 2	Maximum of sixteen (16) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each.	270 F (132 C)	15 minutes	30 minutes
Liquid	Three (3) 1,000 mill-liter containers with vented	250 F (121 C)	45 minutes	0 minutes

	closures. This cycle is intended for non-patient contacting devices only.			
Leak Test	Empty Chamber, test time of 15 minutes.	N/A	N/A	N/A
Warm Up	Empty Chamber	270 F (132C)	4 minutes	3 minutes
Bowie-Dick Test	Bowie-Dick Test Pack	273 F (134 C)	3.5 minutes	2 minutes

Note:

- "IU" means "Immediate Use" cycle.
- Liquid cycle is for non-patient contact use only.

7. Technological Characteristics

Comparison to Predicate Device

Sakura Steam Sterilizer Comparison to Legally Marketed Predicate

Item Description	Sakura Steam Sterilizer ASSR-AO12, -AO12W, -AO12P, -AO12PW / Skytron Integrity 270, 270 VP Steam Sterilizer	Predicate Product (Sakura Steam Sterilizer ASSV-AB09, 09E Skytron Integrity 215, 215 SG Steam Sterilizer, K120149)	Substantially Equivalent or Different
Indication for Use	Sakura Steam Sterilizer / Skytron Integrity Steam Sterilizer is designed and optimized for use in health care facilities. Sakura Steam Sterilizer / Skytron Integrity Steam Sterilizer incorporates high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in	Sakura Steam Sterilizer / Skytron Integrity Steam Sterilizer is designed and optimized for use in health care facilities. Sakura Steam Sterilizer / Skytron Integrity Steam Sterilizer incorporates high-pressure steam to sterilize non-porous and porous, heat and moisture-	Same

	the health care facilities.	stable items and materials used in the health care facilities.	
Electrical	Single Phase, 120VAC, 60Hz	Single Phase, 120VAC, 60Hz	Same
	3 Phases, 208VAC, 60 Hz, 15 Amps. Or, 3 Phase, 480VAC, 60 Hz, 7 Amps. (For Vacuum Pump option)	No Vacuum Pump	Different
Frame	Carbon steel	Carbon steel	Same
Chamber	SUS 316L	SUS 316L	Same
Chamber Size & Volume	26.5 in x 37.5 in x 53 in 32.3 ft3	21.5 in x 21.5 in x 38 in 11.1 ft3	Substantially Equivalent
System Weight – Dry (no utilities, no cabinet)	For Integrity 270: Single Door - 1,516 kg / 3,335 lbs. Double Door – 1,714 kg / 3,771 lbs.	For integrity 215: 760kg / 1675 lbs. For Integrity 215 SG: 830 kg / 1830 lbs.	Substantially Equivalent
Jacket	SUS SA-240 type 304L	SUS SA-240 type 304L	Same
	ASME section VIII, Div. 1	ASME section VIII, Div. 1	Same
Door	SUS 316L, emergency manual door opening system	SUS 316L, emergency manual door opening system	Same
Door	Single or double door (pass through)	Single Door	Substantially Equivalent
Door Opening Method	Manual Swing type (open/close) with power lock-up by elevation of door.	Automated vertical sliding door with foot pedal	Substantially Equivalent.
Door Seal	Steam activated door seal	Steam activated door seal	Same
Insulation	The entire exterior surface of vessel	The entire exterior surface	Same

	is insulated with glass wool insulation materials. Thickness: 25mm Specific gravity: 24kg/m^3	of vessel is insulated with glass wool insulation materials. Thickness: 25mm Specific gravity: 24kg/m^3	
Control Valve	Industrial grade brass or SUS	Industrial grade brass or SUS	Same
	Actuated by electric solenoid or motor or manual shutoff valves.	Actuated by electric solenoid or motor or manual shutoff valves.	Same
Piping	Stainless Steel (SUS 304) or flared copper	Stainless Steel (SUS 304) or flared copper	Same
Safety (pressure relief) valves	ASME approved.	ASME approved.	Same
Steam Source	House steam	House steam or integrated steam generator.	Same
Steam Capacity Requirement (from house steam)	220 lbs./Hour	100 lbs./Hour	Substantially Equivalent.
Vacuum System	Water ejector as standard specification, and the vacuum pump option is available.	Water ejector as standard specification.	Substantially Equivalent
Air Filtration	Cellulose-medium type. Main filter element Material: Polypropylene Pre-filter element Material: Cellulose with phenol impregnated. Two filters are used consisting of one pre-filter and the main filter: Pre-filter: Fuji 6R-60 Main Filter:	Cellulose-medium type. Main filter element Material: Polypropylene Pre-filter element Material: Cellulose with phenol impregnated. Two filters are used consisting of one pre-filter and the main	Same

	PALL (R1F070) with the efficiency of greater than 99.9999% for 0.3 micron particles. (Refer to Exhibit 19 "Filter Information - Pall and Fuji "and Exhibit 21 "Air Filter Replacement Information")	filter: Pre-filter: Fuji 6R-60 Main Filter: PALL (R1F070) with the efficiency of greater than 99.9999% for 0.3 micron particles. (Refer to Exhibit 19 "Filter Information - Pall and Fuji "and Exhibit 21 "Air Filter Replacement Information")	
Control	Automatic operation through all phases of sterilization cycle.	Automatic operation through all phases of sterilization cycle.	Same
	Cycle parameters can be selected and programmed by operator.	Cycle parameters can be selected and programmed by operator.	Same
	All cycle phases are monitored visually.	All cycle phases are monitored visually.	Same
	Cycle completion indications are monitored both audibly and visually.	Cycle completion indications are monitored both audibly and visually.	Same
	Color liquid crystal touch-panel display.	Color liquid crystal touch-panel display.	Same
	Cycle progress and information on time, pressure and temperature, including any fault statements, are indicated on the 40-character	Cycle progress and information on time, pressure and temperature, including any fault statements, are indicated on	Same

	impact printer.	the 40-character impact printer.	
	Factory programmed operation cycles are provided as standardized sterilizing cycles.	Factory programmed operation cycles are provided as standardized sterilizing cycles.	Same
Access (security) Code	Requires entry of a 4-digit access code to operate sterilizer and/or change the cycle values.	Requires entry of a 4-digit access code to operate sterilizer and/or change the cycle values.	Same
Temperature	Temperature readouts are both in Fahrenheit or Centigrade.	Temperature readouts are both in Fahrenheit or Centigrade.	Same
	Impact printer provides recording of time, temperature, pressure, cycle number, sterilizer number and date for each cycle.	Impact printer provides recording of time, temperature, pressure, cycle number, sterilizer number and date for each cycle.	Same
Printer Device	Included as standard. Printed on all pertinent cycle data on 2 1/4 inch wide paper.	Included as standard. Printed on all pertinent cycle data on 2 1/4 inch wide paper.	Same
Integrated Water recirculation system	Stainless Steel reservoir with a brass-recirculating pump, provided as standard.	Stainless Steel reservoir with a brass-recirculating pump, provided as standard.	Same
Factory Programmed Cycle #s (Including Liquid cycle as Option)	8	8	Same
Factory-Programmed Sterilization Cycle - Prevacuum Configuration			
Flash 1 (IU 1)	270 F. (132 C) degree sterilize	270 F. (132 C) degree sterilize	Same

	temp., 3 min. sterilize time, 1 min. dry time. Unwrapped nonporous, a single instrument.	temp., 3 min. sterilize time, 1 min. dry time. Unwrapped nonporous, a single instrument.	
Flash 2 (IU 2)	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 1 min. dry time. Maximum of sixteen (16) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 1 min. dry time. Maximum of six (6) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	Substantially Equivalent
Prevacuum 270	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 30 min. dry time. Maximum of sixteen (16) double wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 30 min. dry time. Maximum of six (6) double wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	Substantially Equivalent
Prevacuum 275	275 F. (135 C) degree sterilize temp., 3 min. sterilize time, 30	275 F. (135 C) degree sterilize temp., 3 min. sterilize time, 30	Substantially Equivalent

	min. dry time. Maximum of sixteen (16) double wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	min. dry time. Maximum of six (6) double wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	
Express Prevacuum (IU 3)	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 3 min. dry time. Maximum of sixteen (16) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	270 F. (132 C) degree sterilize temp., 4 min. sterilize time, 3 min. dry time. Maximum of six (6) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instrument per cycle load.	Substantially Equivalent
Factory-Programmed Sterilization Cycle - Gravity Configuration			
Gravity 1	250 F (121 C) degree sterilize temp. 30 min. sterilize time, 15 min. dry time. Maximum of thirty-two (32) -fabric packs.	250 F (121 C) degree sterilize temp. 30 min. sterilize time, 15 min. dry time. Maximum of twelve (12) -fabric packs.	Substantially Equivalent
Gravity 2	270 F (132 C) degree sterilize temp., 15 min. sterilize time, 30	270 F (132 C) degree sterilize temp., 15 min. sterilize time, 30	Substantially Equivalent

	min. dry time. Maximum of sixteen (16) double wrapped instruments, maximum weight 25 pounds (11.3 kg) per tray.	min. dry time. Maximum of six (6) double wrapped instruments, maximum weight 25 pounds (11.3 kg) per tray.	
Liquid Cycle (Option)	250 F (121 C) degree sterilize temp., 45 min. sterilize time. Maximum of three (3) 1,000 mill-liter containers.	250 F (121 C) degree sterilize temp., 45 min. sterilize time. Maximum of three (3) 1,000 mill-liter containers.	Same
SAL LEVEL Based on ANSI/AAMI ST8: 2008 Section 5.5.2.5-a)	$<10^{-6}$ SAL	$<10^{-6}$ SAL	Same

Discussion of Similarities and Differences

The previously cleared devices and these larger devices utilize the same technology (software) and materials. The only differences are the size of the sterilizers, chamber door (single or double doors) and its opening mechanism, and vacuum system (vacuum system is option). The larger size option is being offered to facilities that need to sterilize a larger quantity of instruments at once. The larger sizes of these models with door and vacuum system differences do not affect the safety and effectiveness of the device.

EFFECTIVENESS:
Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} reduction. **Sakura Seiki Co., Ltd.** validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, the sterilizers were validated to meet the requirements of AAMIIANSI ST8: 2008.

The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document

"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (May 2005).

SAFETY:
The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizer have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards.

The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizercomplies with the following safety standards:

IEC 60601-1-2:2007
IEC61010-1 (2nd Edition) 2008 / CSA C22.2 No.61010-1
IEC61010-2-040: 2005
CISPR11: 2009 ED5.0: AMENDMENT1: 2010
IEC61000-3-2:2005 ED3.0: AMENDMENT1:2010
IEC61000-3-3:2008 ED2.0 (EMC) - PART 3-3
IEC61000-4-2: 2008 ED2.0 (EMC) - PART 4-2
IEC61000-4-3: 2006 ED3.0 +AMENDMENT1: 2007+AMENDMENT2:2010 (EMC)
IEC61000-4-4: 2004 ED2.0 +AMENDMENT1:2010
IEC61000-4-5: 2005 ED2.0
IEC61000-4-6: 2003 ED2.0+AMENDMENT1:2004+AMENDMENT1:2006
IEC61000-4-8: 2009 ED2.0
IEC61000-4-11: 2004 ED2.0
American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section VIII Division 1 2010 Edition: Rules for the Construction of Pressure Vessels.

HAZARDS-FAILURE OF PERFORMANCES
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 the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer's manufacturer's maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incident of sterilizer malfunction or sterilization process failure is relatively rare considering the wide spread use of steam sterilizers. Further,

there are no reports in the literature of patient infection that have resulted from steam sterilizer failure.

The technology designed in the The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizer provide microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

USER INFORMATION

Sakura Seiki Co., Ltd. provides information to the user that is intended to insure safe and effective use of steam sterilization in its detailed User's Manual and other labeling.

Sakura Seiki Co., Ltd. also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

8. **Performance Data:**

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizer. The device passed all of the tests based on pre-determined Pass/Fail criteria.

9. **Conclusions:**

The data from consensus standard testing and comparison to the predicate device show that the The Sakura Steam Sterilizer ASSR-AO12, Sakura Steam Sterilizer ASSR-AO12W, Sakura Steam Sterilizer ASSR-AO12P, Sakura Steam Sterilizer ASSR-AO12PW, Skytron Integrity 270 Steam Sterilizer, and Skytron Integrity 270 VP Steam Sterilizerare as safe and effective as the legally marketed predicate device.

Therefore **Sakura Seiki Co., Ltd.** conclude that the each of the sterilizers included under this submission are substantially equivalent to the predicate device.

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

January 6, 2014

Sakura Seiki Co., Ltd
C/O Ms. Maria F. Griffin
Official Correspondent
55 NORTHERN BLVD SUITE 200
GREAT NECK NY 11021

Re: K132439
Trade/Device Name: Sakura Steam Sterilizer ASSR-A012, ASSR-A012W, ASSR-A012P, ASSR-A012PW, Skytron Integrity 270 Steam Sterilizer and Skytron Integrity 270VP Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 19, 2013
Received: December 23, 2013

Dear Ms. Griffin:

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,

Erin I. Keith

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132439

Device Name:
Sakura Steam Sterilizer ASSR-AO12
Sakura Steam Sterilizer ASSR-AO12W
Sakura Steam Sterilizer ASSR-AO12P
Sakura Steam Sterilizer ASSR-AO12PW
Skytron Integrity 270 Steam Sterilizer
Skytron Integrity 270 VP Steam Sterilizer

Indications For Use:

Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are designed and optimized for use in health care facilities. Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer incorporate high-pressure steam to sterilize non-porous and porous, heat and moisture-stable items and materials used in the health care facilities. Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are available in the following configuration.

26.5" x 37.5" x 53" chamber size, Single or Double Door Prevacuum and Gravity

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 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 -S
2014.01.06 13:55:25 -05'00'

Note:
Sakura Steam Sterilizer ASSR-AO12 is a single door.
Sakura Steam Sterilizer ASSR-AO12W is a double door (pass through).
Sakura Steam Sterilizer ASSR-AO12P is a single door with vacuum pump.
Sakura Steam Sterilizer ASSR-AO12PW is a double door (pass through) with vacuum pump.
Skytron Integrity 270 Steam Sterilizer is a single or double door (pass through).
Skytron 270 VP Steam Sterilizer is a single or double door (pass through) with vacuum pump.

Sakura Steam Sterilizer ASSR-AO12, ASSR-AO12W, ASSR-AO12P and ASSR-AO12PW / Skytron Integrity 270 and 270 VP Steam Sterilizer are equipped with the following factory-programmed sterilization cycle values. The following factory-programmed cycles are validated according to ANSI/AAMI ST8: 2008.

Cycle	Validated Loads	Sterilize Temp	Sterilize Time	Dry Time
Flash 1 (IU 1)	One unwrapped, nonporous instrument no heavier than 0.22 lbs. (100 gram)	270 F (132 C)	3 minutes	1 minute
Flash 2 (IU 2)	Maximum of sixteen (16) unwrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	1 minute
Prevacuum 270	Maximum of sixteen (16) double-wrapped instrument trays, maximum weight 25 pound (11.3kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load.	270 F (132 C)	4 minutes	30 minutes
Prevacuum 275	Maximum of sixteen (16) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen	275 F (135 C)	3 minutes	30 minutes

	instruments per cycle load.			
Express Prevacuum (IU 3)	Maximum of sixteen (16) single wrapped instrument trays, maximum weight 25 pound (11.3 kg) each. The maximum of three (3) 2 mm inside diameter (minimum) and 400 mm long (maximum) lumen instruments per cycle load. This cycle is intended for immediate use and the wrap used for this cycle is not intended to be a sterile barrier.	270 F (132 C)	4 minutes	3 minutes
Gravity 1	Maximum of thirty-two (32) -fabric packs.	250 F (121 C)	30 minutes	15 minutes
Gravity 2	Maximum of thirty-two (32) double-wrapped instrument trays, maximum weight 25 pound (11.3 kg) each.	270 F (132 C)	15 minutes	30 minutes
Liquid	Three (3) 1,000 mill-liter containers with vented closures. This cycle is intended for non-patient contacting devices only.	250 F (121 C)	45 minutes	0 minutes
Leak Test	Empty Chamber, test time of 15 minutes.	N/A	N/A	N/A
Warm Up	Empty Chamber	270 F (132C)	4 minutes	3 minutes
Bowie-Dick Test	Bowie-Dick Test Pack	273 F (134 C)	3.5 minutes	2 minutes

Note:

- Prevacuum 270 - Adjusting the Dry Time to be 15 minutes allows the sterilization of thirty-two (32) fabric packs (maximum).
- Gravity 2 - Adjusting the Steam Purge Time to 10 minutes, the Sterilize Time to 15 minutes, and the Dry Time to 15 minutes allows the sterilization of thirty-two (32) fabric packs (maximum).
- "IU" means "Immediate Use" cycle.
- Liquid cycle is for non-patient contact use only.