November 1, 2019

Sturdy Industrial Co., Ltd
Wolfgang Huang
QA Manager
No. 168 Sec. 1, Zhongxing Road, Wugu District
New Taipei City, 24872 Tw

Re: K181993
Trade/Device Name: STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 23, 2019
Received: October 2, 2019

Dear Wolfgang Huang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*

K181993

Device Name

STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)

Indications for Use *(Describe)*

The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable equipment. Dental handpieces can be sterilized in the models SA-260MA and SA-260MA-R. The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is not recommended for sterilization of liquid intended for direct patient contact. Cycle parameters are as follows:

Cycle	Ster. Temp.	Ster. Pressure	Ster. Time (minutes)	Dry Time (minutes)	Items to be Sterilized (always consult the item manufacturer's recommendation for sterilization)
Un-wrapped	270 °F (132 ℃)	27.2 psi (186 kPa)	3	30	● Instruments loose on a tray. ● Loose items manufacturers recommend for exposures at 270 °F (132 ℃) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*
Wrapped (Pouches)	270 °F (132 ℃)	27.2 psi (186 kPa)	4	30	● Pouched or loosely wrapped instruments. ● Wrapped trays of loose instrument. ● Wrapped items manufacturers recommend for exposures at 270 °F (132 ℃) for 4 minutes.
Wrapped (Textile Packs)	250 °F (121 ℃)	15 psi (104 kPa)	30	30	● Textiles and surgical packs wrapped for sterilization. ● Items except liquids, manufacturers recommend for exposures at 250 °F (121 ℃) for 30 minutes.
Handpieces	270 °F (132 ℃)	27.2 psi (186 kPa)	4	30	Dental handpieces (wrapped) *Note: Verify acceptability of sterilization parameters with handpiece manufacturer.*
Bowie-Dick test	273 °F (134 ℃)	29.5 psi (203 kPa)	3.5	N/A	N/A
Re-Dry	N/A	N/A	N/A	10	N/A
Pump test	N/A	N/A	N/A	10	N/A

Maximum load:

		Program			
		Unwrapped	Wrapped	Wrapped	Handpieces
Temperature		270 °F (132 ℃)	250 °F (121 ℃)	270 °F (132 ℃)	270 °F (132 ℃)
Pressure		27.2 psi (186 kPa)	15 psi (104 kPa)	27.2 psi (186 kPa)	27.2 psi (186 kPa)
Sterilization time (minutes)		3	30	4	4
Dry time (minutes)		30	30	30	30
Max. load	Solid Instrument	9.0 lbs (4080 grams)	-	-	-
	Textile Packs	-	2.9 lbs (1300 grams)	-	-
	Pouches		-	2.9 lbs (1300 grams)	
	Handpieces	-	-	-	9 handpieces with other instruments 4.5 lbs (2040 grams)

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.

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510(k)Summary
(K181993)

The information required by 21 CFR § 807.92 is listed below.

Submitter:	STURDY Industrial CO., LTD. No. 168, Sec. 1, Zhongxing Rd, Wugu District, New Taipei City 24872, Taiwan	
Contact Person:	Wolfgang Huang +886-2-2981-25245 #601	
Date prepared:	December 24, 2018	
Device Names:	Proprietary:	STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)
	Common:	Steam sterilizer
	Classification:	21 CFR § 880.6880 FLE: Sterilizer, steam
	Class	II

Predicate Device Information:

Midmark M11 Ultraclave Steam Sterilizer, K990189.

General Description:

The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) uses saturated steam at high pressures and temperatures and kills infectious bio-organisms. This steam is generated inside the sterilization chamber by an electric heating element. The sterilizer's electronic control system is pre-programmed to complete sterilization cycles according to established time, temperature and pressure parameters.

Devices to be sterilized are placed in the sterilization chamber. The operator chooses a sterilization cycle and presses the appropriate switch. The sterilizer automatically fills the chamber, heats the water into steam,

four times pulse sterilizes the items, and automatically vents the steam and cools the chamber after sterilization is complete.

Indications for Use:

The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable equipment. Dental handpieces can be sterilized in the models SA-260MA and SA-260MA-R. The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is not recommended for sterilization of liquid intended for direct patient contact. Cycle parameters are as follows:

Cycle	Ster. Temp.	Ster. Pressure	Ster. Time (minutes)	Dry Time (minutes)	Items to be Sterilized (always consult the item manufacturer's recommendation for sterilization)
Un-wrapped	270 °F (132 ℃)	27.2 psi (186 kPa)	3	30	● Instruments loose on a tray. ● Loose items manufacturers recommend for exposures at 270 °F (132 ℃) for 3 minutes. *Note: The sterility of unwrapped items is compromised on exposure to a non-sterile environment.*
Wrapped (Pouches)	270 °F (132 ℃)	27.2 psi (186 kPa)	4	30	● Pouched or loosely wrapped instruments. ● Wrapped trays of loose instrument. ● Wrapped items manufacturers recommend for exposures at 270 °F (132 ℃) for 4 minutes.
Wrapped (Textile Packs)	250 °F (121 ℃)	15 psi (104 kPa)	30	30	● Textiles and surgical packs wrapped for sterilization. ● Items except liquids, manufacturers recommend for exposures at 250 °F (121 ℃) for 30 minutes.
Handpieces	270 °F (132 ℃)	27.2 psi (186 kPa)	4	30	Dental handpieces (wrapped) *Note: Verify acceptability of sterilization parameters with handpiece manufacturer.*
Bowie-Dick test	273 °F (134 ℃)	29.5 psi (203 kPa)	3.5	N/A	N/A
Re-Dry	N/A	N/A	N/A	10	N/A
Pump test	N/A	N/A	N/A	10	N/A

Maximum load:

		Program			
		Unwrapped	Wrapped	Wrapped	Handpieces
Temperature		270 °F (132 ℃)	250 °F (121 ℃)	270 °F (132 ℃)	270 °F (132 ℃)
Pressure		27.2 psi (186 kPa)	15 psi (104 kPa)	27.2 psi (186 kPa)	27.2 psi (186 kPa)
Sterilization time (minutes)		3	30	4	4
Dry time (minutes)		30	30	30	30
Max. load	Solid Instrument	9.0 lbs (4080 grams)	-	-	-
	Textile Packs	-	2.9 lbs (1300 grams)	-	-
	Pouches		-	2.9 lbs (1300 grams)	
	Handpieces	-	-	-	9 handpieces with other instruments 4.5 lbs (2040 grams)

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Technological Characteristics:

Shown below is the technological characteristic comparison of the STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) with the predicate device, MidMark M11:

Device Characteristic	STURDY Autoclave Super Microm (K181993)		Predicate MidMark M11 (K990189)	Comment
	SA-260MA	SA-260MA-R		
Intended Use	The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable equipment. Dental handpieces can be sterilizer in the SA-260MA and SA-260MA-R. The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is not recommended for sterilization of liquid intended for direct patient contact.		The M11UltraClave is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable equipment. Dental handpieces can be sterilizer in the M11 in the Pouches cycle. This device is not recommended for sterilization of liquid intended for direct patient contact.	Similar
Product code Regulation Class	FLE 880.6880 Steam Sterilizer Class II		FLE 880.6880 Steam Sterilizer Class II	Same
Built according to Standard	ANSI/AAMI ST55:2016		ANSI/AAMI ST55:2010/(R)2014	Similar
Sterilization type	moist heat sterilization		moist heat sterilization	Same

Device Characteristic	STURDY Autoclave Super Microm (K181993)		Predicate MidMark M11 (K990189)	Comment
	SA-260MA	SA-260MA-R		
Power Source	Single Phase, 120VAC, 60Hz, 12 A		Single Phase, 115VAC, 60Hz, 12 A	Similar
Water Reservoir Capacity	1.1 Gallons (4.2 liters) to Full Mark		1.4 Gallons (5.3 liters) to Full Mark	Similar
Electrical safety standard	IEC 61010-1, 3rd Edition IEC 61010-2-040:2015		UL 61010-1, 2nd Edition IEC 61010-2-040, 1st Edition	Similar
Certification	ASME Boiler & Pressure Vessel Code, Section VIII, Division 1.		ASME Boiler & Pressure Vessel Code, Section VIII, Division 1.	Same
Pressure vessel				
Chamber design standard	ASME Boiler & Pressure Vessel Code, Section VIII, Division 1.		ASME Boiler & Pressure Vessel Code, Section VIII, Division 1.	Same
Material of chamber	corrosion-resistant properties		corrosion-resistant properties	Same
Safety Valve Setting	40 psi (275.8 kPa)		40 psi (275.8 kPa)	Same
Safety (pressure relief) valves	ASME approved		ASME approved	Same
Control system				
Sterilization Method	Dynamic-air-removal steam sterilizer		Dynamic-air-removal steam sterilizer	Same
Control Technology	Microcontrollers		Microcontrollers	Same
Sterilization process	Temperature sensor for exposure temperature monitoring		Temperature sensor for exposure temperature monitoring	Same

Device Characteristic	STURDY Autoclave Super Microm (K181993)		Predicate MidMark M11 (K990189)	Comment
	SA-260MA	SA-260MA-R		
monitoring				
Process control	Automatic operation through all phases of sterilization cycle,		Automatic operation through all phases of sterilization cycle,	Same
Control devices				
generate steam	electrical heaters		electrical heaters	Same
Performance:				
Biological performance Comply with	SAL of 10^{-6} Through achievement of no growth at half cycle with validation loads. ANSI/AAMI ST55:2016		SAL of 10^{-6} Through achievement of no growth at half cycle with validation loads. ANSI/AAMI ST55:2010/(R)2014	Similar
Moisture retention				
Textile test packs Comply with	The gain in weight due to moisture content shall be less than 2 %. ANSI/AAMI ST55:2016		The gain in weight due to moisture content shall be less than 2 %. ANSI/AAMI ST55:2010/(R)2014	Similar
Wrapped instrument test trays Comply with	The gain in weight due to moisture content shall be less than 0.5 % ANSI/AAMI ST55:2016		The gain in weight due to moisture content shall be less than 0.5 % ANSI/AAMI ST55:2010/(R)2014	Same
Maximum Loading capacities				
Factory predefined cycles				
Unwrapped	Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 3 minutes		Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 3 minutes	Similar

Device Characteristic	STURDY Autoclave Super Microm (K181993)		Predicate MidMark M11 (K990189)	Comment
	SA-260MA	SA-260MA-R		
	Drying cycle: 30 minutes		Drying cycle: 30 minutes (Dry time can be changed from 0 to 60 minutes.)	
Pouches	Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 4 minutes Drying cycle: 30 minutes		Temp.: 270°F (132°C) Pressure:27.1psi (186 kPa) Sterilize: 5 minutes Drying cycle: 30 minutes (Dry time can be changed from 0 to 60 minutes.)	Similar
Packs	Temp.: 250° F(121° C) Pressure: 15 psi (104 kPa) Sterilize: 30 minutes Drying cycle: 30 minutes		Temp.: 250° F(121° C) Pressure: 15 psi (104 kPa) Sterilize: 30 minutes Drying cycle: 30 minutes (Dry time can be changed from 0 to 60 minutes.)	Similar
Handpieces	Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 4 minutes Drying cycle: 30 minutes		Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 6 minutes Drying cycle: 30 minutes (Dry time can be changed from 0 to 60 minutes.)	Similar

Summary of Non-Clinical Testing:

Shown below the standards that were used to demonstrate that the subject device met the acceptance criteria for the standards listed below:

Test Method / Name	**Purpose**	**Acceptance Criteria**	**Results**
ANSI/AAMI ST55:2016 Empty chamber (Temperature mapping) - Unwrapped Program, 270 ºF (132 ºC), sterilization time 3 minutes, dry time 30 minutes.	To ensure that the sterilizer is capable of providing steady-state thermal conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load	the chamber temperature during the exposure time remains within +3 ℃ (or +6 ℉) and -0 ℃ (or -0 ℉)	Pass
- Wrapped (Pouch) Program, 270 ºF (132 ºC), sterilization time 4 minutes, dry time 30 minutes.			Pass
- Wrapped (Textile Packs) Program, 250 ºF (121 ºC), sterilization time 30 minutes, dry time 30 minutes.			Pass
- Handpiece Program, 270 ºF (132 ºC), sterilization time 4 minutes, dry time 30 minutes.			Pass
- Bowie-Dick Test Program, 273 ºF (134 ºC), sterilization time 3.5 minutes, dry time 0 minutes.			Pass
ANSI/AAMI ST55:2016	To verify the air removal	The Bowie-Dick test indicator sheet shall	Pass

- Bowie-Dick test Cycle Program, 273 ºF (134 ºC), sterilization time 3.5 minutes, dry time 0	performance of target sterilizer	show a uniform color change; i.e., the color in the center should be the same as that at the outer edges.	
ANSI/AAMI ST55:2016 Moisture Retention Testing for wrapped instrument test trays Wrapped, 270 ºF (132 ºC), Ster. time 4 minutes, Dry time 30 minutes	To verify the presence of any residual moisture of wrapped instrument test trays	No evidence of condensed moisture (visible droplets) is allowed. The gain in weight due to moisture content shall be less than 0.5%.	Pass
ANSI/AAMI ST55:2016 Moisture Retention Testing for wrapped instrument test trays (for paper-plastic peel pouches) - Wrapped 270 ºF (132 ºC) Cycle to perform sterilization time 4 minutes and the dry time 30 minutes	To verify the presence of any residual moisture of wrapped instrument test trays	No evidence of condensed moisture (visible droplets) is allowed.	Pass
ANSI/AAMI ST55:2016 Moisture Retention Testing for Textile test pack - Wrapped (Textile Packs) Program, 250 ºF (121 ºC), sterilization time 30 minutes, dry time 30 minutes	To verify the presence of any residual moisture of textile test pack	No evidence of condensed moisture (visible droplets) is allowed. The gain in weight due to moisture content shall be less than 2.0%	Pass
ANSI/AAMI ST55:2016 Biological performance with wrapped instrument PCD (BI test tray)	To verify the Biological performance with wrapped instrument PCD (BI test tray)	The recommended cycle has a 10^{-6} SAL PCD is used	Pass

- three consecutive cycles run at one-half the recommended holding time, e.g. 132℃ for 2 minutes, under worst-case maximum load condition			
ANSI/AAMI ST55:2016 Biological Performance with Dental Handpiece - one-half the recommended holding time, e.g. 132℃ for 2 minutes	To verify the biological performance with instrument PCD	No growth observed in the vials containing turbines or in the extraction of any of the turbines, except for the positive controls. No growth shall be observed with the BIs except the positive control BI. If growth is observed for test or negative control vials/extractions/BIs, the presence of the test organism shall be verified via Gram stain, or equivalent. Growth should be observed for the positive control turbine and BI	Pass
ANSI/AAMI ST55:2016 Biological performance with a textile PCD -Program Wrapped (Packs): Cycle Program: Wrapped (Packs) Sterilization Temperature: 250°F (121°C) Exposure Time: 15 minutes (half	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biologically challenged	The recommended cycle has a 10^{-6} SAL	Pass

cycles) Dry Time: 30 minutes			
-Program Wrapped (Packs): Sterilization Temperature: 270°F (132°C) Exposure Time: 2 minutes (half cycles) Dry Time: 30 minutes			Pass

Shown below are a listing of Standards used in the non-clinical testing of the subject devices

Item	Standards
1	ANSI/AAMI ST55:2016
2	EN ISO 14971:2012
3	ISO 13485:2016
4	IEC/EN 61010-1:2010 (Third Edition)
5	IEC 61010-2-040:2015
6	American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels Ed. 2015

Clinical Data:

No clinical data is required for this device classification submission.

CONCLUSION:

Based on the conclusions drawn from the nonclinical tests that demonstrate that the STURDY Steam Sterilizers models SA-260MA and SA-260MA-R is as safe, as effective, and performs as well as or better than the legally marketed predicate device, MidMark M11 (K990189).