6/21/23

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

Re: K231489
Trade/Device Name: Sturdy Autoclave Super Microm
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: May 22, 2023
Received: May 23, 2023

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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231489

Device Name
STURDY Autoclave Super Microm

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	20	● 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	20	● 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	20	● 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	20	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

		Program			
		Unwrapped	Wrapped	Wrapped	Handpieces
Temperature		270 °F (132 °C)	250 °F (121 °C)	270 °F (132 °C)	270 °F (132 °C)
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)		20	20	20	20
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.

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

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510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.

The assigned 510(k) Number: **K231489**
Date Prepared: **20 June 2023**

1. **Submitter**

Mailing Address	STURDY Industrial CO., LTD. No. 168, Sec. 1, Zhongxing Rd, Wugu District, New Taipei City 24872, Taiwan Phone: +886-2-2981-25245 #601 Establishment Registration No.:
Contact Person	Wolfgang Huang
Phone:	+886-2-2981-25245 #601
E-mail:	wolfgang@sturdy.com.tw

2 **Device Name**

Common or usual name	Steam Sterilizer
Trade Name	STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R)
Product Code	FLE
Device	Sterilizer, Steam
CFR Classification	21 CFR § 880.6880
Device Class	II
Classification Panel	General Hospital

3 **Predicate k number** K181993

4 **Device Description:** The STURDY Autoclave Super Microm (models SA-260MA and SA-260MA-R) is a table-top steam sterilizers that uses saturated steam at high pressures and

temperatures and kills infectious bio-organisms. The 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 the established time, temperature, and pressure parameters.

Items to be sterilized are placed in the sterilization chamber. The user selects a sterilization cycle, and presses the start switch to initiate the cycle. The sterilizer will automatically fill water into the chamber, heat the water into steam, introduce steam-flush and pressure-pulses, hold at a set pressure, temperature, and time to sterilize the items, and automatically vent the steam and cool the chamber down after the sterilization is complete.

5.	**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.
	Special Conditions for Use Statement(s):	N/A
6.	**Technological Characteristics Comparison**	Modifications in the pressure vessel supplier and several operational features optimization, and the reduced overall air removal time and dry time while the air removal, drying, and sterilization performance remained

Comparison with Predicate:

intact. These modifications applied to both models of the previously 510(k) cleared devices (K181993), the model numbers are SA-260MA and SA-260MA-R.

A comparison of the device features, intended use, and other information summarized in **Table 6.1**.

Table 6.1: Technological Characteristics Comparison Table

Models	Predicate Devices (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)	Modified Device (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)
510(k) Number	**K181993**	**K231489**
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.	Same.
Product Code	FLE	Same
C.F.R. code **Class**	880.6880 Steam Sterilizer II	Same
Built according to standard	ANSI/AAMI ST55	Same
Electrical safety standard	IEC 61010-1 IEC 61010-2-040	Same
Sterilization type	moist heat sterilization	Same
Power Source	Single Phase, 120VAC, 60Hz, 12A	Same
Water reservoir capacity	1.1 Gallons (4.2 liters) to Full Mark	Same

Models	Predicate Devices (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)	Modified Device (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)
510(k) Number	**K181993**	**K231489**
Pressure vessel		
Chamber design standard	ASME Boiler & Pressure Vessel Code, Section VIII, Division 1.	Same
Chamber size	10.2 in. diameter × 17.7 in. depth (26cm x 45cm)	Same
Chamber capacity	6.3 Gallons (24 liters)	Same
Materials of the chamber	Corrosion-resistance materials (SUS 304 or SUS 316)	Same
Safety (pressure relief) valve setting	40 psi (275.8 kPa) ASME approved	Equivalent 40 psi (275.8 kPa) to 41 psi (282.7 kPa) Max. ASME approved
Sterilization method	Dynamic-air-removal steam sterilizer 4 steam-flush pressure-pulse	Equivalent Dynamic-air-removal steam sterilizer 2 steam-flush pressure-pulse
Control technology	Microcontrollers	Same
Sterilization process monitoring	Temperature sensor for exposure condition monitoring	Same

Models	Predicate Devices (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)	Modified Device (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)
510(k) Number	**K181993**	**K231489**
Process control	Automatic operation through all phases of sterilization cycle	Same

Models	Predicate Devices (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)	Modified Device (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)
510(k) Number	**K181993**	**K231489**
Cycle phases	Factory predefined cycles are provided as standardized sterilizing cycles, including: ● Unwarpped instruments: Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 3 minutes Drying cycle: 30 minutes ● Wrapped instruments (Packs): Temp.: 250° F(121° C) Pressure: 15 psi (104 kPa) Sterilize: 30 minutes Drying cycle: 30 minutes ● Wrapped instruments (pouches): Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 4 minutes Drying cycle: 30 minutes ● Handpieces: Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 6 minutes Drying cycle: 30 minutes	Equivalent. The drying performance has been successfully verified using the reduced dry time. Factory predefined cycles are provided as standardized sterilizing cycles, including: ● Unwarpped instruments: Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 3 minutes Drying cycle: 20 minutes ● Wrapped instruments (Packs): Temp.: 250° F(121° C) Pressure: 15 psi (104 kPa) Sterilize: 20 minutes Drying cycle: 30 minutes ● Wrapped instruments (pouches): Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 4 minutes Drying cycle: 20 minutes ● Handpieces: Temp.: 270°F (132°C) Pressure: 27.1psi (186 kPa) Sterilize: 6 minutes Drying cycle: 20 minutes

Models	Predicate Devices (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)	Modified Device (STURDY Autoclave Super Microm models SA-260MA and SA-260MA-R)
510(k) Number	**K181993**	**K231489**
Cycle end	Cycle completion indications are monitored both audibly and visually	Same
Steam generator	Electrical heaters	Same
Control valve	Actuated by electric solenoid	Same
Recorder	SA-260MA: NA SA-260MA-R: Digital recorder	Same
Biological performance	SAL of 10^{-6} Through achievement of no growth at half cycle with validation loads, including textile PCD, wrapped instrument PCD, and dental handpieces, in compliance with ANSI/AAMI ST55:2016	Same
Moisture retention	Meet the moisture retention test criteria in ANSI/AAMI ST55:2016 for textile test packs, wrapped instrument test trays, and paper-plastic peel pouches	Same
Maximum loading capacities	Solid items: 150 instruments – 9.0lbs (4082 grams) Handpieces: 9 handpieces in a rack and 75 instruments Packs: 930 in^3(<= 2 in. thick) 15240 cm^3 (<= 5 cm thick)	Same

7. Summary of non-clinical testing

The modified device has passed the following non-clinical testing to verify its safety and effectiveness.

Test Method / Name	Purpose
ANSI/AAMI ST55:2016 - Empty chamber temperature mapping	to ensure that the modified device is capable of providing steady-state thermal conditions within the chamber consistent with the desired sterility assurance level (SAL) in the load
ANSI/AAMI ST55:2016 - Bowie-Dick test	to verify the air removal performance of the modified device
ANSI/AAMI ST55:2016 Moisture Retention Testing	to verify the presence of any residual moisture
ANSI/AAMI ST55:2016 Biological performance	to verify the Biological performance to achieve the required sterility assurance level
Safety tests according to UL 61010-1 3.1 Ed., and IEC 61010-2-040 3rd Ed. 2020-05	To verify that the modified device meets all the applicable safety requirements for electrical equipment specified in the standard
Electromagnetic Compatibility and Electrical Safety tests according to EN IEC 61326-1:2021, and associated standards	To verify that the modified device meets all the applicable electromagnetic compatibility and electrical safety requirements for electrical equipment specified in the standard
Software verification and validation tests	To verify that software of the modified device meets the safety and functional requirements and fulfills the user need.

8. Clinical data

No clinical data is required to verify the modified device and demonstrate the substantial equivalence.

9. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device K181993.