June 6, 2025

Ningbo Ican Machines Co., Ltd.
% Lord Guo
Regulatory Director
Orscene (shanghai) Medical Technology Co., Ltd.
Room 118, Building 20, No. 1-42, Lane 83, Hongxiang North Rd
Lingang New Zone, China (Shanghai) Pilot Free Trade Zone
Shanghai, Shanghai
China

Re: K243994
Trade/Device Name: Steam Sterilizer (2545D)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: May 5, 2025
Received: May 5, 2025

Dear Lord Guo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.06.06 14:53:47 -04'00'

for: Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243994

Device Name
Steam Sterilizer (2545D)

Indications for Use *(Describe)*
The 2545D tabletop Steam Sterilizer is designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical & dental offices).

The 2545D was validated for use in:
Unwrapped instruments, wrapped instruments, sterilizing dental handpieces and textiles/porous loads.

Key cycles of subject device

#	Cycle name	Sterilization temperature (F°/℃)	Sterilization time (min)	Numbers of vacuum pulses	Dry time (min)	Load type	Max. load(kg)
1	Quick 273	273/134	4	1	4	Unwrapped solid material	5.00
2	Universal 273	273/134	4	3	20	Unwrapped solid material	5.00
						wrapped solid or hollow material	4.50
						Unwrapped porous material	1.25
						wrapped porous material	1.10
3	Universal 250	250/121	30	3	20	Unwrapped solid material	5.00
						wrapped solid or hollow material	4.50
						Unwrapped porous material	1.25
						wrapped porous material	1.10
4	BD TEST 273	273/134	3.5	3	20	/	/
5	Vacuum test	/	/	/	/	/	/

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K243994

1. ADMINISTRATIVE INFORMATION

Applicant Name	Ningbo Ican Machines Co., Ltd.
Applicant Address	No. 77 Yunlin East Road, Gulin Town, Haishu District Ningbo Zhejiang 315000 China
Applicant Contact Telephone	0574-89011155
Applicant Contact	Mr. HUI LIN
Applicant Contact Email	Sales@icanclave.com
Correspondent Name	Orscene (shanghai) Medical Technology Co., Ltd.
Correspondent Address	Room 118, Building 20, No. 1-42, Lane 83, Hongxiang North Road Lingang New Zone, China (Shanghai) Pilot Free Trade Zone shanghai shanghai China
Correspondent Contact Telephone	18521500818
Correspondent Contact	Mr. Lord Guo
Correspondent Contact Email	lord.guo@orscene.net
Date summary prepared	June 3, 2025

2. SUBJECT DEVICE

Device Trade Name: Steam Sterilizer (2545D)
Common Name: Steam sterilizer
Classification Name: Sterilizer, Steam
Regulatory Number: 880.6880
Product Code: FLE

3. PREDICATE DEVICE

Manufacturer: Shinva Medical Instrument Co., Ltd.
Device name: MOST-T Autoclave
510(K) number: K220102
Product Code: FLE

4. DEVICE DESCRIPTION

The subject device (model: 2545D) is a table-top steam sterilizer intended for use by a health care provider to sterilize medical products by means of pressurized steam.

The 2545D uses steam as a sterilizing agent. The steam for the sterilization process is produced by warming up a controlled amount of demineralized water that is inserted into a pipe heating element and then flows

into the chamber as steam. This technique is used as a way of reducing water consumption and saving energy. The subject device is equipped with a heating element wrapped around the chamber to maintain the required temperatures and steam for the sterilization process. All of these processes are done via the computerized control system of the device.

The 2545D Sterilizers are designed to automate the sterilization process, to the extent possible, and the user interface on the subject device extends this capability to include sterilization record keeping. To use the sterilizer, the operator fills the water reservoir with water (distilled or purified) and loads the included trays with properly cleaned and prepped instruments for sterilization. The loaded trays are then placed inside the chamber, and the chamber door is manually closed by the operator. Based on the cycle parameters that are appropriate for the type of load being processed, the operator then selects the appropriate sterilization cycle on the user interface. Once the cycle is selected and the operator presses "Start," the sterilizer then automatically performs all the operations necessary to complete the sterilization process without further interaction from the operator. The sterilization cycle is composed of several phases which include Filling, Heating, Sterilization, Venting, and Drying. Sterilization parameters and process status also displayed on the screen.

The 2545D is designed with some external port and printing function:

- The device features one built-in USB ports to enable the operation of an external USB device to record sterilization cycles.
- The device features built-in report printer to print the sterilization records;
- The device features built-in memory to record up to 16000 sterilization cycles; these can be exported to a USB device to be transferred to a PC;
- The device features built-in label printer to print labels with a unique cycle ID barcode, Program name, and expiry dates.

The label printer and report printer are optional additions to the subject device

Device specifications are provided below:

Chamber size (mm)	250x450
Overall dimensions (mm)	490(W) x 455(H) x 690(D)
Net Weight (kg)	50
Nominal power (VA)	1750
Rated Voltage (V)	120
Rated frequency (Hz)	60
Capacity of the distilled water tank (L)	4.0 L (Water at level Max.) Approx. 0.8L (Water at level Min.) Approx.
Operation temperature (°C)	5-40
Operation relative humidity	Max. 80%, non-condensing
Atmospheric pressure (kPa)	76-106
Max. allowed working pressure (MPa)	~0.28
Relief valve (MPa)	~0.28

5. INDICATIONS FOR USE

The 2545D tabletop Steam Sterilizer is designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities. (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical & dental offices).
The 2545D was validated for use in:
Unwrapped instruments, wrapped instruments, sterilizing dental handpieces and textiles/porous loads.

Key cycles of subject device

#	Cycle name	Sterilization temperature (F°/℃)	Sterilization time (min)	Numbers of vacuum pulses	Dry time (min)	Load type	Max. load(kg)
1	Quick 273	273/134	4	1	4	Unwrapped solid material	5.00
2	Universal 273	273/134	4	3	20	Unwrapped solid material	5.00
						wrapped solid or hollow material	4.50
						Unwrapped porous material	1.25
						wrapped porous material	1.10
3	Universal 250	250/121	30	3	20	Unwrapped solid material	5.00
						wrapped solid or hollow material	4.50
						Unwrapped porous material	1.25
						wrapped porous material	1.10
4	BD TEST 273	273/134	3.5	3	20	/	/
5	Vacuum test	/	/	/	/	/	/

6. TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO THE PREDICATE

The following tables provide a side-by-side comparison of the 2545D to the predicate device to support this pre-market notification.

Comparison Table of the Subject Device and Predicate Device

Intended Use / Indications for Use Comparison

Comparison Elements	Subject Device	Predicate Device K220102	Comments
Indications for Use	The 2545D tabletop Steam Sterilizer is designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities (e.g., hospitals, nursing homes, extended-care facilities, freestanding surgical centers, clinics, and medical & dental offices).	The MOST-T Autoclave is a table-top autoclave designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (e.g., dental hand pieces; suction pipes) in ophthalmic, dental, medical clinics; and in first aid rooms.	Same
Comparison Statement	Both the subject device and predicate devices are designed for the sterilization of medical and surgical goods such as wrapped and unwrapped solid, hollow, and porous loads used in health care facilities.		

Technological and Performance Characteristics Comparison			
Comparison Elements	**Subject Device** K243994	**Predicate Device** K220102	**Comments**
Sterilization cycles	Quick 273 for Unwrapped solid material 4 min/134℃/4min Universal 273 for Unwrapped solid material, wrapped solid or hollow material, Unwrapped or wrapped porous material 4 min/134℃/20min Universal 250 for Unwrapped solid material, wrapped solid or hollow material, Unwrapped or wrapped porous material 30 min/121℃/20min	N-QUICK for single unwrapped solid instrument 4 min/134℃/1min B-QUICK for single unwrapped hollow instrument 4 min/134℃/1min B134UNIV for Packaged or unpackaged instrument or textile 4 min/134℃/20min B121UNIV for Packaged or unpackaged instrument or textile 20 min/121℃/20min USER for Packaged or unpackaged instrument 4 min/134℃/20min	Similar See note 1
Max. load	Unwrapped solid material: 5kg wrapped solid or hollow material: 4.5kg Unwrapped porous material: 1.25kg wrapped porous material:1.10kg	Max. weight of instrument: 5.5kg Max. weight of textile: 0.8kg	Similar See note 1
Chamber volume/size	This device is a single door table-top autoclave with a chamber volume of: 22L; Size:Φ250mm×450mm	This device is a single door table-top autoclave with a chamber volume of: 24L; Size:Φ250mm×450mm	Similar See note 1

Control system	The device is software controlled with electronic control panel that permits automatic usage. The device is nonprogrammable.	The device is software controlled with electronic control panel that permits automatic usage. The device is nonprogrammable.	Same
Materials	The chamber and door are made of a corrosion-resistant 304L stainless steel.	The chamber and door are made of a corrosion-resistant 304L stainless steel.	Same
User Interface	LCD Display and touch pad	LCD Display Screen and key pad	Same
Door Gaskets	High Temperature Silicon Rubber	High Temperature Silicon Rubber	Same
Door lock	Manual to drive the door lock hook rotation, the door lock hook directly pull the door tightly locked structure	Door motor work to drive the door lock hook rotation, the door lock hook directly pull the door tightly locked structure	Different See note 2
Door safety interlock	the sterilizer can start the working procedure only when the door is closed in place; the door cannot be opened when the inner chamber is under pressure	the sterilizer can start the working procedure only when the door is closed in place; the door cannot be opened when the inner chamber is under pressure	Same
Overpressure valve	ASME pressure relief valve	ASME pressure relief valve	Same
Overheat Protection	Thermostat@250°C	Automatic overheat protection	Similar
Energy source	The device can be operated only while connected to an electrical source (the electrical grid). AC 120V 60 Hz 1750VA	The device can be operated only while connected to an electrical source (the electrical grid). AC 120V 60 Hz 1.5KVA	Similar
Operation principle	The operation principle is sterilization by heating a controlled amount of demineralized water to generate steam as the sterilization reagent and maintaining its temperature by using a heating element surrounding the chamber. The water is drawn from a built-in water reservoir. The subject device has a vacuum mechanism to allow better air removal of air pockets in the load for an effective sterilization and to allow drying of the load at the end of the sterilization process.	The operation principle is sterilization by heating a controlled amount of demineralized water to generate steam as the sterilization reagent and maintaining its temperature by using a heating element surrounding the chamber. The water is drawn from a built-in water reservoir. The predicate device has a vacuum mechanism to allow better air removal of air pockets in the load for an effective sterilization and to allow drying of the load at the end of the sterilization process.	Same
Performance	Comply with AAMI ST55:2016 requirements	Comply with AAMI ST55:2016 requirements	Same

Comparison Statement	Note 1: 1) The subject device and predicate device have similar Sterilization cycles: - The subject device has Universal 250 with the holding time 30min which is longer than the predicate device B121 UNIV's 20min, this holding time difference cannot rise safety and effectiveness concerns based on performance tests according to AAMI ST55; - The subject device's Quick 273 cycle has a drying time 4min which is longer than the predicate device's N-QUICK and B-QUICK's 1min, this drying time difference cannot rise safety and effectiveness concerns based on performance tests according to AAMI ST55. 2) The subject device has similar rated max. load - The rated max. load difference cannot rise safety and effectiveness concerns based on performance tests according to AAMI ST55. 3) The subject device has same chamber size but smaller rated volume with a difference 2L, this rated chamber volume difference cannot rise safety and effectiveness concerns based on performance tests according to AAMI ST55. Note 2: 1) The subject device uses manual force via handle to lock the door, and the Predicate device uses motor driving. These two measures both meet safety requirements of UL 61010-1, IEC 61010-2-040 and AAMI ST55. This different does not rise safety and effectiveness concerns.

7. SUMMARY OF TESTING and PERFORMANCE STANDARDS

To establish the technical equivalency of the Steam Sterilizer, evaluations were conducted to confirm compliance with performance requirements, including

Non-Clinical Performance Data		
Evaluation	**Standards Used**	**Results**
Safety	ANSI/UL 61010-1 Third Edition 5/12/2012 / Revised 7/19/2019, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements	Passed; the results of the evaluation demonstrate compliance of the device to the standards.
	IEC 61010-2-040:2020 Edition 3.0 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-040: Particular requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials	
	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers	
EMC	IEC 60601-1-2 Edition 4.1 2020-09	Passed; the results of the

	Consolidated Version Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests	evaluation demonstrate compliance of the device to the standards
Software	IEC 62304- 2006+A1:2015 Medical device software - Software life cycle processes	Meeting standard specification
Performance- Bowie & Dick	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers To verify air removal performance	Passed, the Bowie-Dick test indicator sheet showed a uniform color change
Performance- Air leaks	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers To verify air removal performance	Passed, the average leak rate is 0.0133kPa/min
Performance- Temperature control	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers To verify 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	Passed. The chamber temperature during the exposure time remains within +3℃ and -0℃ of selected sterilization exposure temperature for cycles Quick 273, Universal 273 and Universal 250
Performance- Biological performance	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers To verify biological performance with textile PCD, wrapped instrument PCD and dental handpieces	Passed. The results showed that the tested cycle has a 10^{-6} SAL or an SAL providing a greater assurance of sterility. There shall be no growth observed in the vials containing turbines or in the extraction of any of the turbines.
Performance- Moisture retention	ANSI/AAMI ST55:2016 Table-Top Steam Sterilizers To verify the drying performance for cycles Quick 273, Universal 273 and Universal 250 with Textile PCD, wrapped instruments and paper-plastic pouch	Passed. The results showed that the gain in weight less than 2% and 0.5% for Textile PCD and wrapped instruments respectively, no water droplets for paper-plastic pouch.

8. Conclusion:

The conclusion drawn from the testing demonstrates that the subject device is at least as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K220102, Class II (21 CFR 880.6880, Product Code FLE).