August 14, 2025

Guangzhou Ajax Medical Equipment Co., Ltd.
℅ Iris Fung
Regulation Manager
SGS-CSTC Standards Technical Services Co., Ltd.
198 KEZHU Road SCIENTECH Park Guangzhou Economic
& Technology Development District
GuangZhou, Guangdong 510000
China

Re: K250164
Trade/Device Name: Cassette Autoclave (ACA5)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: July 15, 2025
Received: July 15, 2025

Dear Iris Fung:

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,

PAULO LARANJEIRA -S

Digitally signed by PAULO LARANJEIRA -S
Date: 2025.08.14 14:05:37 -04'00'

for: Stephen Anisko
Acting Assistant 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)*
K250164

Device Name
Cassette Autoclave (ACA5

Indications for Use *(Describe)*
The Cassette Autoclave (ACA5 is suitable for the sterilization of dental and medical instruments designed to withstand steam sterilization. The Cassette Autoclave (ACA5) has not been designed to sterilize liquids, bio-medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the autoclave.

Please refer to below sterilization cycles for Program Name / Load Description/Sterilization Temperature/Sterilization Time/Drying Time and Load Weight.:

1)Program Name: 134 ℃
Load Description:
Solid objectssmall porous objects, narrow-clearance items, dental handpieces and textile, wrapped or unwrapped.
Sterilization Temperature : 134 ℃273°F
Sterilization Time: 4 minutes
Drying Time: 60minutes
Load Weight: 0.9 kg

2)Program Name: 121℃
Load Description:
Solid objectssmall porous objects, narrow-clearance items, dental handpieces and textile, wrapped or unwrapped.
Sterilization Temperature : 121 ℃250°F
Sterilization Time: 30 minutes
Drying Time: 60 minutes
Load Weight: 0.9 kg

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.

510(k) Summary K250164

In accordance with the requirement of 21 CFR 807.92.

Date of the summary prepared: August 14, 2025

1. Submitter's Information

Sponsor

- Company Name: Guangzhou Ajax Medical Equipment Co., Ltd.
- Address: Building No.2, Dagang Industrial Zone, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, 511447, P.R. China
- Phone: +86- 13247083152
- Contact Person (including title): Dien Wang Registered Engineer
- E-mail: manting.wang@ajaxdent.cn

Application Correspondent

- Company: SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic &
- Technology Development District, Guangzhou, Guangdong, CHINA
- Tel: 86-13247083152
- Email: jianda-lee@foxmail.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Steam sterilizer
- Trade Name: Cassette Autoclave（ACA5）
- Classification Name: Dental Operative Unit and Accessories
- Review Panel: General Hospital
- Product Code: FLE
- Regulation Number: 880.6880
- Regulation Class: II

3. Predicate Device Information

	Predicate Device
Sponsor	Enbio Group AG
Device Name	Enbio S
510(k) Number	K210279
Product Code	FLE

Regulation Number	880.6880
Regulation Class	II

4. Device Description

The Cassette Autoclave (ACA5) is a dynamic-air-removal (pre-vacuum) table-top steam sterilizer intended for use by a health care provider to sterilize medical products by means of pressurized steam. The Cassette Autoclave (ACA5) consists of five modules: water supply, disinfection, air dry, exhaust steam processing and control system.

The main working principle is as follows: The water supply module supplies clean distilled water to the disinfection module. Inside the steam generator, the electric heating element generates high- temperature saturated steam at 121℃ for a period of 4 minutes and 134℃ for a period of 30 minutes. This steam is then utilized within a sealed disinfection box to sterilize instruments. During sterilization, excess high- temperature steam is condensed in the exhaust steam processing module. After the sterilization, high- temperature steam and coolant water remain inside the disinfection box. Air dry cycle works for ventilation and drying. Ultimately, you can get the dry and sterile instruments.

Basic parameters/use conditions/power supply specifications are as follows:

Name	Cassette Autoclave （ACA5）	
Machine Dimensions (A*B*C)	650mm*416mm*200mm	
Cassette Sizes (D*E*F)	495mm*196mm*78.5mm	
Maximum Load for a Single Sterilization	1.5kg	
Sterilization Chamber Volume	5.1L	
Weight (Without water)	43KG	
Rated Operating Temperature	134℃	
Rated Working Pressure	212kPa（Gauge Pressure）	
Relief Valve Pressure Setting	Pressure set: 300kpa (relative pressure), pressure release when exceeded	
Operating Temperature Range	121℃～134℃	
Reservoir Volume	4L	
Input Voltage	a.c.110v，60Hz	
Rated Power	1300VA	
Fuse(250VH15AT)	10A	
Working Medium	Steam	
Illumination level	(215±15) lx to (1500±15) lx	
Operating Mode	Non--continuous operation, with a maximum of 6 cycles per hour.	
Water Supply	Purified water	

Noise	Less than 70dB	
Service life	10 years	

5. Intended Use / Indications for Use

The Cassette Autoclave (ACA5) is suitable for the sterilization of dental and medical instruments designed to withstand steam sterilization. The Cassette Autoclave (ACA5) has not been designed to sterilize liquids, bio- medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the autoclave.

Please refer to below sterilization cycles for Program Name / Load Description/Sterilization Temperature/Sterilization Time/Drying Time and Load Weight.:

Program Name	Load Description	Sterilization Temperature	Sterilization Time	Drying time	Max load
134 ℃	Solid objects, small porous objects, narrow-clearance items, dental handpieces and textile, wrapped or unwrapped.	134 ℃（273°F）	4 minutes	60 minutes	0.9 kg
121 ℃	Solid objects, small porous objects, narrow-clearance items, dental handpieces and textile, wrapped or unwrapped.	121 ℃（250°F）	30 minutes	60 minutes	0.9 kg

6. Comparison to predicate device

Elements of Comparison	Subject Device	Predicate Device I	Verdict
510(k) Number	K250164	K210279	--
Device Name	Cassette Autoclave (ACA5)	Enbio S(K210279)	--
Product Code	FLE	FLE	Same
Regulation Number	21 CFR 880.6880	21 CFR 880.6880	Same
Regulation Class	II	II	Same
Prescription	Over-The-Counter	Over-The-Counter	Same

Intended Use	The Cassette Autoclave (ACA5) is suitable for the sterilization of dental and medical instruments designed to withstand steam sterilization. The Cassette Autoclave (ACA5) has not been designed to sterilize liquids, bio-medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the autoclave.	The Enbio S is an air - removal (pre - vacuum) table - top steam sterilizer intended for use by a health care provider to sterilize medical products by means of pressurized steam. It is suitable for the sterilization of dental and medical instruments that are validated to be sterilized by steam. The Enbio S has not been designed to sterilize liquid loads, bio - medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the autoclave.	Similar
Water tank	Internal reservoir	External	Different
Sterilization Chamber Volume	5.1 L	2.7 L	Different
Sterilization Chamber Dimensions (L x W x H)	495mm*196mm*78.5mm	292 x 192 x 45 mm (L x W x H)	Different
Device Dimensions (L x W x H)	650mm*416mm*200mm	561 x 252 x 162 mm	Different
Weight	43KG	15 kg (approximately)	Different
Power Rating	a.c.110v，60Hz，10A	110 - 120 V, 60Hz, 15A	Similar
Wireless Transmission Capability	No	No	Same
USB Port	Yes	Yes	Same
Sterility and Shelf - life	Not provided sterile. No shelf - life claimed	Not provided sterile. No shelf - life claimed	Same

7. Non-clinical Bench (Performance) testing

The device had been validated to comply with the following bench testing:

Test Method	Purpose	Acceptance criteria	Result
ANSI AAMI ST55:2016 Vacuum Test	Verify air removal performance	Average leak rate of 1 milliliter of mercury (mmHg) (0.13 kPa) (0.019 psia) per min or less	Pass
Bowie Dick Test	Verify air removal performance	The Bowie - Dick - test indicator sheet shall show a uniform color change, i.e., the color in the center should be the same as that at the outer edges.	Pass
Hollow unwrapped (S) 134˚C/4min	Verify temperature control performance	The chamber temperature during the exposure time remains within +3 ºC and –0 ºC of the selected sterilization exposure temperature.	Pass
Solid unwrapped(N) 134˚C/4min			
Hollow wrapped(S) 134˚C/4min			
Rubber/plastic(S) 121˚C/30min			

Test Method	Purpose	Acceptance criteria	Result
Hollow unwrapped(S) 134˚C/4min	Verify pressure control performance	The chamber pressure is within ±0.3 bar within the chamber.	Pass
Solid unwrapped(N) 134˚C/4min			
Hollow wrapped(S) 134˚C/4min			
Rubber/plastic(S) 121˚C/30min			
Hollow unwrapped(S) 134˚C/4min/dry 60min	Verify Moisture retention performance	There shall be no visible moisture present on the outside of loads or on the instruments contained inside. In addition, weighing before and after sterilization shall reveal less than 2% moisture gain in the PCD (textile test pack) and less than 0.5% moisture gain in the PCD (wrapped instrument test tray).	Pass
Solid unwrapped(N) 134˚C/4min/dry 60min			
Hollow wrapped(S) 134˚C/4min/dry 60min			
Rubber/plastic(S) 121˚C/30min/dry 60min			
Hollow unwrapped(S) 134˚C/4min/dry 60min	Verify Biological performance	When the sterilizer is tested, biological indicators (BIs) and spore suspensions shall show no growth of the test spores. The recommended exposure time shall have a sufficient lethality to reduce a microbial population having a D121 °C value of at least 1.0 minute (min) to a 10-6 probability of a surviving organism—that is, an overkill method shall be used, and the test results shall otherwise meet the acceptance criteria defined in the particular test.	Pass
Solid unwrapped(N) 134˚C/4min/dry 60min			
Hollow wrapped(S) 134˚C/4min/dry 60min			
Rubber/plastic(S) 121˚C/30min/dry 60min			
IEC61010-1:2010/AMD1:2016 IEC 61010-2-040:2020	Verify electrical safety	Meets specifications of standard	Pass
IEC 61326-1:2020	Verify electromagnetic compatibility	Meets specifications of standards	Pass

Test Summary

The Cassette Autoclave (ACA5) was evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

- **Electrical safety test**
  IEC 61010-1:2010/AMD1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
  IEC 61010-2-040:2020 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

- **Table-top steam sterilizers test**
  ANSI/AAMI ST55:2016/(R)2023 Table-top steam sterilizers

- **Software verification and validation test**
  FDA “Guidance for Premarket Submissions and for Software Contained in Medical Devices”

- **Software Life Cycle Processes**
  IEC 62304:2006+AMD1:2015 Medical Device Software

8. Summary for clinical test

Clinical performance is not deemed necessary.

9. Conclusion

The nonclinical test result demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device, K210279.