February 26, 2026

Enbio Group AG
Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k, Saint Paul, MN 55114 USA
(763) 682-4139 [phone]
(763) 682-4420 [fax]

Re: K260254
Trade/Device Name: Enbio PRO
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 27, 2026
Received: January 27, 2026

Dear Prithul Bom:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

CHRISTOPHER K. DUGARD -S

Christopher K. Dugard, M.S.
Division 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)*
K260254

Device Name
Enbio PRO

Indications for Use *(Describe)*
The Enbio PRO 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 PRO has not been designed to sterilize liquid loads, biomedical 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 the table below for program name, load description, sterilization temperature, exposure time, drying time and maximum load.

Program Name	Load Description	Sterilization Temperature	Sterilization Time	Drying Time	Maximum Load
134°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, and textiles; wrapped and unwrapped	134°C (273°F)	4 minutes	4 minutes	1.6 Kg/ 3.52 lbs
121°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, textiles, and plastics; wrapped and unwrapped	121°C (250°F)	30 minutes	5:30 minutes	1.6 Kg/ 3.52 lbs
134°C FAST*	solid objects, non-porous objects, simple instruments (such as scissors, handles, pliers, chisels, probes, etc.), and dental handpieces; unwrapped. *Immediate Use Steam Sterilization cycle	134°C (273°F)	4 minutes	N/A	1.6 Kg/ 3.52 lbs

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
K260254

1. Sponsor/ Applicant

Enbio Group AG
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Summary Preparation Date: February 23, 2026

2. Device

Trade Name	Enbio PRO
Classification	Class 2
Classification Name	Steam Sterilizer
Product Code	FLE
Regulation Number	21 CFR 880.6880
Review Panel	General Hospital

3. Predicate Device

Enbio S (K213991)

4. Device Description

The Enbio PRO 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 has a hermetically sealed, heated chamber made from aluminum, with two heaters sink inside chamber walls. Inside this chamber, the sterilized load is placed on a special perforated tray. After closing the chamber, the user selects the appropriate sterilization program through the TFT touch screen.

The actual sterilization phase starts after the pre-vacuum phase. The aluminum steam generator produces superheated steam and applies it inside the chamber. That steam penetrates the sterilized instruments. The set temperature is maintained inside the chamber depending on the selected sterilization cycle (121C° or 134°C), during a specified time (30 minutes or 4 minutes). After that time all the steam accumulated inside the chamber is pumped out and the drying cycle begins. When sterilization is finished, device displays to the user that process is completed, and that the load is sterile. The user can then safely open the chamber and remove tools.

5. Indications for Use

The Enbio PRO 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 PRO 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.

Please refer to the table below for program name, load description, sterilization temperature, exposure time, drying time and maximum load.

Program Name	Load Description	Sterilization Temperature	Sterilization Time	Drying Time	Maximum Load
134°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, and textiles; wrapped and unwrapped	134˚C (273˚F)	4 minutes	4 minutes	1.6 Kg/ 3.52 lbs
121°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, textiles, and plastics; wrapped and unwrapped	121°C (250˚F)	30 minutes	5:30 minutes	1.6 Kg/ 3.52 lbs
134°C FAST*	solid objects, non-porous objects, simple instruments (such as scissors, handles, pliers, chisels, probes, etc.), and dental handpieces; unwrapped. *Immediate Use Steam Sterilization cycle	134˚C (273˚F)	4 minutes	N/A	1.6 Kg/ 3.52 lbs

6. Technological Characteristics Comparison Table

A comparison between the proposed 'Enbio PRO' and the predicate device 'Enbio S' is provided as follows:

	Subject Device	**Predicate Device**	**Comparison**
Trade Name	**Enbio PRO**	**Enbio S (K213991)**	**–**
Submitter	Enbio Group AG	Enbio Group AG	Same
Product Code	FLE	FLE	Same
Regulation Number	21 CFR 880.6880	21 CFR 880.6880	Same
Device Class	Class 2	Class 2	Same
Prescription / Over-The-Counter Use	Over-The-Counter	Over-The-Counter	Same
Intended Use/ Indications for use (the specific sterilization cycles and parameters are compared on Page 3)	The Enbio PRO 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 PRO 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.	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.	Same
Sterilization Cycle / Program	• 134°C • 121°C • 134°C FAST (Immediate Use Steam Sterilization cycle)	• 134°C • 121°C • 134°C FAST (Immediate Use Steam Sterilization cycle)	Same

	Subject Device	Predicate Device	Comparison
Trade Name	**Enbio PRO**	**Enbio S (K213991)**	**–**
Sterilization Chamber Volume	5.3 L	2.7 L	Different
Sterilization Chamber Dimensions	300 x 200 x 90 mm (L x W x H)	292 x 192 x 45 mm (L x W x H)	Different
Device Dimensions (L x W x H)	561 x 270 x 202 mm	561 x 252 x 162 mm	Different
Weight	20 kg (approximately)	15 kg (approximately)	Different
Power Rating	110-120 V, 60Hz, 15A	110-120 V, 60Hz, 15A	Same
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

The sterilization cycle/ program specifications (program name, load description, sterilization temperature, exposure time, drying time and maximum load) are compared as follows:

Enbio PRO (subject of this Traditional 510k)

Program Name	Load Description	Sterilization Temperature	Sterilization Time	Drying Time	Maximum Load
134˚C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, and textiles; wrapped and unwrapped	134˚C (273˚F)	4 minutes	4 minutes	1.6 Kg/ 3.52 lbs
121°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, textiles, and plastics; wrapped and unwrapped	121°C (250˚F)	30 minutes	5:30 minutes	1.6 Kg/ 3.52 lbs
134°C FAST*	Solid objects, non-porous objects, simple instruments (such as scissors, handles, pliers, chisels, probes, etc.), and dental handpieces; unwrapped. *Immediate use Steam Sterilization cycle	134˚C (273˚F)	4 minutes	N/A	1.6 Kg/ 3.52 lbs

Enbio S (K213991)

Program Name	Load Description	Sterilization Temperature	Sterilization Time	Drying Time	Maximum Load
134˚C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, and textiles; wrapped and unwrapped	134˚C (273˚F)	4 minutes	3 minutes	0.5 Kg/ 1.1 lbs
121°C	solid objects, small porous objects, simple objects recessed, narrow-clearance items, dental handpieces, textiles, and plastics; wrapped and unwrapped	121°C (250˚F)	30 minutes	5 minutes	0.5 Kg/ 1.1 lbs
134°C FAST*	Solid objects, non-porous objects, simple instruments (such as scissors, handles, pliers, chisels, probes, etc.), and dental handpieces; unwrapped. *Immediate use Steam Sterilization cycle	134˚C (273˚F)	4 minutes	N/A	0.5 Kg/ 1.1 lbs

The intended use and general indications for use of the Enbio PRO and Enbio S are same as both devices are air-removal (pre-vacuum) table-top steam sterilizers intended for use by a health care provider to sterilize medical products by means of pressurized steam. They are suitable for the sterilization of dental and medical instruments that are validated to be sterilized by steam. Both devices are not designed to sterilize liquid loads, bio-medical waste or materials not compatible with steam sterilization.
Their specific indications for use differ with respect to the exposure time, drying time and maximum load, as discussed below.

The Enbio PRO has a larger sterilization chamber and maximum load capacity compared to the Enbio S. Therefore, the weight and dimensions of the two devices are slightly different. The exposure times and drying times (for the sterilization programs offered by the two devices) are slightly different; however, these parameters are within the standard values established for the respective sterilization temperatures. Also, the performance and effectiveness of the Enbio PRO for all sterilization programs and load types has been validated per AAMI ANSI ST55:2016. In addition, the Electrical Safety of the Enbio PRO is demonstrated through testing conducted in compliance with standards IEC 61010-1 and IEC 61010-2-040. The Electromagnetic Compatibility (EMC) of Enbio PRO is demonstrated through testing conducted in compliance with IEC 60601-1-2.

Also, the firmware for Enbio PRO is updated (since the clearance of Enbio S under K213991) to support these differences. The updated firmware has been validated using the same methodology that was used to validate the software and firmware for the predicate Enbio S cleared under K213991.

7. Non-clinical Bench (Performance) testing

The Electrical Safety of the Enbio PRO is demonstrated through testing conducted in compliance with standards IEC 61010-1 and IEC 61010-2-040.

The Electromagnetic Compatibility (EMC) of the Enbio S is demonstrated through testing conducted in compliance with IEC 60601-1-2.

The performance and effectiveness of the Enbio PRO is demonstrated through validation conducted in compliance with AAMI ANSI ST55:2016. Below table includes a summary of the performance test conducted per ANSI AAMI ST55:2016.

ANSI AAMI ST55:2016 Test Method	**Purpose**	**Acceptance Criteria**	**Results**
Vacuum Test	Verify air removal performance	Average leak rate shall be equal to or less than 1 mmHg (i.e. 0.13 kPa or 0.019 psia) per minute over the measured time interval	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
Full Cycle Study	Verify pressure and temperature – to ensure that the sterilizer is capable of providing steady-state thermal and pressure conditions during the cycle	Temperature recorded shall be between +3°C /- 0°C of the sterilization temperature for specified program. Pressure recorded shall be within ±0.3 bar of the equipment's specified pressure	Pass
Half Cycle Study	Verify pressure and temperature – to ensure that the sterilizer is capable of providing steady-state thermal and pressure conditions during the cycle	Temperature recorded shall be between +3°C /- 0°C of the sterilization temperature for specified program. Pressure recorded shall be within ±0.3 bar of the equipment's specified pressure	Pass
Half Cycle Study, Over-Kill Biological Performance with Dental Turbine	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biological challenge	The tested cycle demonstrates a 10^{-6} Sterility Assurance Level (SAL)	Pass

ANSI AAMI ST55:2016 Test Method	Purpose	Acceptance Criteria	Results
Full Cycle Biological Indicators	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biological challenge	The tested cycle demonstrates a 10^{-6} Sterility Assurance Level (SAL)	Pass
Half Cycle Biological Indicators	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biological challenge	The tested cycle demonstrates a 10^{-6} Sterility Assurance Level (SAL)	Pass
Half Cycle Biological Indicators - Turbine	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biological challenge	The tested cycle demonstrates a 10^{-6} Sterility Assurance Level (SAL)	Pass

8. Clinical Testing

The submission does not contain any data from clinical testing.

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the Enbio PRO is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Enbio S (K213991).