



February 22, 2022

Enbio Group AG
Lukasz Rogowski
Corporate Quality Manager
Eichengasse 3
Oensingen, CH-4702
Switzerland

Re: K213991

Trade/Device Name: Enbio S
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 25, 2022
Received: January 26, 2022

Dear Lukasz Rogowski:

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,

Clarence W. Murray, III, PhD
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

Indications for Use

510(k) Number (if known)
K213991

Device Name
Enbio S

Indications for Use (Describe)

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.

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	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

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 - 213991

1. Sponsor/ Applicant

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Mr. Lukasz Rogowski
Corporate Quality Manager
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+48 605 058 629

Summary Preparation Date: January 25, 2022

2. Device

Trade Name	Enbio S
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 (K210279)

4. Device Description

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 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 (121°C 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. Enbio S also features an additional sterilization cycle referred to as '134°C FAST' which is an immediate use steam sterilization cycle without drying. When sterilization is finished, device displays to the user that process is completed, and that the load is sterile.

5. Indications for Use

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.

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	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

6. Technological Characteristics Comparison Table

Provided below is a technological comparison of the subject device with the predicate device.

	Subject Device	Predicate Device	Comparison
Trade Name	Enbio S	Enbio S (K210279)	
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	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.	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	<ul style="list-style-type: none"> • 134°C • 121°C • 134°C FAST (Immediate Use Steam Sterilization cycle) 	<ul style="list-style-type: none"> • 134°C • 121°C 	Different
Water tank	External	External	Same
Sterilization Chamber Volume	2.7 L	2.7 L	Same
Sterilization Chamber Dimensions	292 x 192 x 45 mm (L x W x H)	292 x 192 x 45 mm (L x W x H)	Same
Device Dimensions (L x W x H)	561 x 252 x 162 mm	561 x 252 x 162 mm	Same
Weight	15 kg (approximately)	15 kg (approximately)	Same
Power Rating	110-120 V, 60Hz, 15A	110-120 V, 60Hz, 15A	Same

	Subject Device	Predicate Device	Comparison
Trade Name	Enbio S	Enbio S (K210279)	
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 intended use, fundamental scientific technology, design, construction, materials, and electrical characteristics of the proposed Enbio S are identical to the Enbio S cleared under K210279.

The only modification is the addition of a '134°C FAST' program, which is an Immediate Use Steam Sterilization (IUSS) cycle with following parameters. The indications for use are modified to describe this new program/ sterilization cycle. The labeling (User Manual), software and firmware are also updated to support this additional program.

The Enbio S cleared under K210279 did not have a '134°C FAST' IUSS cycle; however the following previously 510(k) cleared device serves as 'reference device' to support the addition of the IUSS cycle.

- Statclave G4 Chamber Autoclave (K190062)

The Statclave G4 Chamber Autoclave has IUSS cycle parameters of 132°C for 4 minutes (and no drying) whereas the proposed Enbio S has '134°C FAST' IUSS cycle parameters of 134°C for 4 minutes (and no drying). Although, their IUSS cycle temperatures are slightly different, the performance and effectiveness of the Enbio S 134°C FAST program has been validated per AAMI ANSI ST55:2016. In addition, the updated software and firmware have been validated using the same methodology that was used to validate the software and firmware of Enbio S cleared under K210279.

7. Non-clinical Bench (Performance) testing

Below table includes a summary of the performance test conducted per ANSI AAMI ST55:2016 to validate the performance of the Enbio S '134°C FAST' Immediate Use Steam Sterilization cycle.

In addition, the updated software and firmware have been validated using the same methodology that was used to validate the software and firmware of Enbio S previously cleared under K210279.

ANSI AAMI ST55:2016 Test Method	Purpose	Acceptance criteria	Results (see details provided in Table 2)
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	To ensure the efficacy of the equipment and the lethality of the recommended processing parameters by biological	The tested cycle has a 10 ⁻⁶ Sterility Assurance Level (SAL)	Pass

ANSI AAMI ST55:2016 Test Method	Purpose	Acceptance criteria	Results (see details provided in Table 2)
with Dental Turbine	challenge		
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 has 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 has 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 has 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 S is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Enbio S (K210279).