October 29, 2021

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

Re: K210279
Trade/Device Name: Enbio S
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 24, 2021
Received: September 27, 2021

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, Ph.D.
Assistant Director
THT4B1:Sterility Devices Team
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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)*

K210279

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

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
K210279

1. Sponsor/ Applicant

Enbio Group AG
Eichengasse 3
CH-4702 Oensingen, Switzerland

Mr. Lukasz Rogowski
Corporate Quality Manager
Email: lukasz.rogowski@enbio.com
Phone: +48 605 058 629

Summary Preparation Date: October 29, 2021

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

Statclave G4 Chamber Autoclave (K190062)

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 (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.

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

6. Technological Characteristics Comparision Table

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

	Subject Device	**Predicate Device**	**Comparison**
Trade Name	**Enbio S**	**STATCLAVE G4 Chamber Autoclave (K190062)**	
Submitter	Enbio Group AG	SciCan Ltd.	-
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 STATCLAVE G4 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. It is suitable for the sterilization of dental and medical instruments that are validated to be sterilized by steam. The STATCLAVE G4 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
Water tank	External	Internal reservoir	Different
Sterilization Chamber Volume	2.7 L	26 L	Different
Sterilization Chamber Dimensions	292 x 192 x 45 mm (L x W x H)	Diameter: 280 mm Depth: 381 mm	Different
Device Dimensions (L x W x H)	561 x 252 x 162 mm	635 x 450 x 495 mm	Different

Weight	15 kg (approximately)	62.7kg (approximately)	Different
Power Rating	110-120 V, 60Hz, 15A	120V, 60Hz, 12 A	Similar
Wireless Transmission Capability	No	Yes	Different
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

Provided below is the non-clinical testing to demonstrated the subject device meets the specification and accpetance criteria found in the Standards and test method listed below.

Test Method	Purpose	Acceptance criteria	Result
ANSI AAMI ST55:2016 Vacuum Test	Verify air removal performance	Average leak rate of 1 millimeter 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
ANSI AAMI ST55:2016 Empty Chamber Study • 134˚C (273˚F) in 4 minutes	Verify pressure and temperature – to ensure that the sterilizer is capable of providing steady-state thermal and pressure conditions within the chamber	+3°C/-0°C ±0.3 bar	Pass
ANSI AAMI ST55:2016 Empty Chamber Study • 121°C (250˚F) in 30 minutes			Pass
ANSI AAMI ST55:2016 Full Cycle Study • 134˚C (273˚F) in 4 minutes	Verify pressure and temperature – to ensure that the sterilizer is capable of providing steady-state thermal and pressure conditions during the cycle	+3°C/-0°C ±0.3 bar	Pass
ANSI AAMI ST55:2016 Full Cycle Study • 121°C (250˚F) in 30 minutes			Pass
ANSI AAMI ST55:2016 Half Cycle Study • 134˚C (273˚F) in 4 minutes	Verify pressure and temperature – to ensure that the sterilizer is capable of providing	+3°C/-0°C ±0.3 bar	Pass

ANSI AAMI ST55:2016 Half Cycle Study • 121°C (250˚F) in 30 minutes	steady-state thermal and pressure conditions during the cycle		Pass
ANSI AAMI ST55:2016 Full Cycle Biological Indicators • 134˚C (273˚F) in 4 minutes	To verify biological sterilization performance	The tested cycle has a 10^{-6} SAL	Pass
ANSI AAMI ST55:2016 Full Cycle Biological Indicators 121°C (250˚F) in 30 minutes			Pass
ANSI AAMI ST55:2016 Half Cycle Biological Indicators • 134˚C (273˚F) in 2 minutes	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} SAL	Pass
ANSI AAMI ST55:2016 Half Cycle Biological Indicators • 121°C (250˚F) in 15 minutes			Pass
ANSI AAMI ST55:2016 Half Cycle Study / Textile PCD • 134˚C (273˚F) in 2 minutes	Verify half-cycle sterilization of BI inside textile PCD	The tested cycle has a 10^{-6} SAL	Pass
ANSI AAMI ST55:2016 Half Cycle Study / Textile PCD • 121°C (250˚F) in 15 minutes			Pass
IEC 61010-1, 61010-2	Verify electrical safety	Meets specifications of standard	Pass
IEC 60601-1-2, IEC 61326-1, 47 CFR 15 Subpart B, ICES-003:2016	Verify electromagnetic compatibility	Meets specifications of standards	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, STATCLAVE G4 Chamber Autoclave (K190062).

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