January 30, 2025

Laboratorios Biogalenic, S.A. DE C.V.
Roberto Quiñonez
Plant Director
Calle Claper, Blvd. Del Ejercito Nacional km 5.5, Soyapango
San Salvador, SV 1639
El Salvador

Re: K242717
Trade/Device Name: Laboratorios Biogalenic Sterile Water for Inhalation, USP
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: January 3, 2025
Received: January 3, 2025

Dear Roberto Quiñonez:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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OHT1: Office of Ophthalmic, Anesthesia,
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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.

Submission Number *(if known)*

K242717

Device Name

Laboratorios Biogalenic Sterile Water for Inhalation, USP

Indications for Use *(Describe)*

Sterile Water for Inhalation, USP is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings.

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

STERILE WATER FOR INHALATION, USP

APPLICANT

Company Name	:	Laboratorios Biogalenic, S.A. DE C.V.
Company Address	:	Calle Claper, Blvd. Del Ejercito Nacional km 5.5, Soyapango, San Salvador, 1639 SV
Company Phone	:	+503-2227-4133 EXT 106
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Contact Person	:	Roberto Quiñonez
Designation	:	Plant Director
Phone	:	+503-2227-4133 EXT 106
Email	:	r.q@biogalenic.com.sv
Date Summary Prepared	:	July 25th , 2024

DEVICE IDENTIFICATION

Common Name of the device	Sterile Water for Inhalation, USP
Device Trade Name	Laboratorios Biogalenic Sterile Water for Inhalation, USP
Device Classification Name	Respiratory gas humidifier
Device Regulation Number	21 CFR 868.5450
Device Classification	Class II
Product code	BTT
Classification Panel	Anesthesiology

PREDICATE DEVICE

Laboratorios Biogalenic S.A. de C.V. identified the following legally marketed device as substantially equivalent:

Predicate Device	Applicant	510(k) Number
Sterile Water for Inhalation 1L Flexoval® Bottles	Hometa Inc	K223551

DEVICE DESCRIPTION

Sterile Water for Inhalation, USP is a sterile, single-dose medical device provided in durable Polypropylene (PP) bottles, which are resistant to breakage and designed for safe and easy handling. The bottles are available with two types of closures:

- A 36 mm PP screw cap with a PP/PET aluminium induction seal
- A 28mm bromobutyl stopper with an aluminium seal

The bottles are available in the following volume configurations:

- 1000mL PP bottles with either a bromobutyl stopper and aluminium seal, or a PP/PET aluminium induction seal, PP screw cap, and tamper-evident plastic shrink wrap.
- 500mL PP bottles with a PP/PET aluminium induction seal, PP screw cap, and tamper-evident plastic shrink wrap.

Sterile Water for Inhalation, USP is not for parenteral administration or irrigation. The product is For Inhalation Therapy Only. It is supplied sterile and intended for single use only. Discard any unused portion.

INDICATIONS FOR USE

The Sterile Water for Inhalation, USP is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings.

NON-CLINICAL PERFORMANCE TESTING

PHYSICOCHEMICAL AND BIOLOGICAL TESTING: The tests listed below for Sterile Water for Inhalation, USP were performed using USP methods and internally validated procedures. The following tests were conducted on the subject device.

- Total Organic Carbon (TOC)
- Water Conductivity
- Process Bioburden
- Volume in Container
- Sterility
- Bacterial Endotoxin
- Appearance

Based on these tests, Laboratorios Biogalenic S.A. de C.V. has demonstrated that the device functions as intended, supporting substantial equivalence.

PACKAGING TESTS

Specific tests conducted on the device demonstrate that it performs as intended and supports substantial equivalence. The results from the tests indicate compliance with the criteria for each test and provide valuable data on the expected performance of the packaging, ensuring it functions as required. The observed results are:

- **Resistance to Leakage (ASTM D3078-02):** No leaking or deformation of bottles.
- **Hermeticity (ASTM F1929-23):** Compliance with hermeticity requirements.
- **Resistance to Pressure (ASTM F1140/F1140M):** The device withstands the required pressure limits.
- **Resistance to Rupture (ASTM D642):** The device resists rupture under specified conditions.
- **Resistance to Damage from Dropping Tests (ISO 15747:2018):** The device remains intact and functional after dropping tests.

These results validate the device packaging integrity and durability, confirming its suitability for the intended use.

BIOCOMPATIBILITY

Biocompatibility testing performed in accordance with ISO 10993-1:2018: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process. The following testing were performed to demonstrate substantial equivalence:

- *In Vitro* Cytotoxicity (L929 Cell Line) conducted per ISO 10993-5:2009, Third Edition: Biological Evaluation of Medical Devices: Tests for *in vitro* cytotoxicity
- Sensitization (Guinea Pig Maximization Test) conducted per ISO 10993-10:2021 Fourth Edition: Biological Evaluation of Medical Devices: Tests for Skin Sensitization
- Intracutaneous Reactivity conducted per ISO 10993-12:2021, First Edition: Biological Evaluation of Medical Devices: Tests for Irritation
- Material Mediated Pyrogenicity conducted per ISO 10993-11:2017 Third Edition: Biological Evaluation of Medical Devices: Tests for Systemic Toxicity
- Extractable/leachable testing per ISO 10993-18:2020/Amd1:2022:Biological Evaluation of Medical Devices: Chemical Characterization of Medical Devices within a Risk Management Process
- Toxicological risk assessment conducted per ISO 10993-17:2023 Biological Evaluation of Medical Devices: Establishment of Allowable Limits for Leachable Substances on the Detected Chemicals within the Extract

STERILIZATION VALIDATION

The sterilization process was performed in accordance with PDA Technical Report No. 1 (Revised 2007), FDA Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products, ISO 17665 Sterilization of Health care Products-Moist Heat, which outlines the validation of moist heat sterilization processes, including cycle design, development, qualification, and ongoing control. This process was qualified and is considered robust for controlling hold times during sterilization. The Sterile Water for Inhalation, USP, was validated for sterilization using steam-air to achieve a Sterility Assurance Level (SAL) of 10^{-6}. Geobacillus stearothermophilus, known for its resistance to moist heat, was used as a biological indicator, and no growth was observed

after being subjected to the sterilization cycle and after incubated for 48 hours at 55°C ± 2 °C no growth occurred indicating that the sterilization conditions were achieved . This process ensures that the Sterile Water for Inhalation, USP is sterile at the point of use. The product was sterilized at 121°C to 122°C for a period of 108 minutes.

SUBSTANTIAL EQUIVALENCE

The comparison between the subject device and the predicate device shows that both devices have the same indications for use, specifically, providing a supply of sterile water for inhalation to humidifier chambers. Both devices share the same BTT classification and are manufactured using the same sterile water as the primary material, packaged in disposable plastic containers. They are similar in design and technological characteristics. Various physicochemical, performance, and biological testing have demonstrated that differences in primary packaging and sterilization temperatures do not pose any significant issues. The subject device functions as intended.

The following Substantial Equivalence Comparison Table summarizes the key features of the subject device compared to the predicate device.

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
510(k) Number	This Submission	K223551	-
Manufacturer	Laboratorios Biogalenic S.A. de C.V.	Hometa Inc	-
Device Trade Name	Laboratorios Biogalenic Sterile Water for Inhalation, USP	Sterile Water for Inhalation in 1L Flexoval ® Bottles	-
Generic/ Common Name	Sterile Water for Inhalation, USP	Sterile Water for Inhalation	-
Regulation Number	21 CFR 868.5450	21 CFR 868.5450	Same
Regulation Name	Respiratory Gas Humidifier	Respiratory Gas Humidifier	Same
Classification Panel	Anesthesiology	Anesthesiology	Same
Device Class	Class II	Class II	Same
Product Code	BTT	BTT	Same

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Indication For Use	Sterile Water for Inhalation, USP is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non-institutional care settings.	The Sterile Water for Inhalation Flexoval® Bottle is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers. It is intended to be used in institutional and non- institutional care settings by qualified staff. The Sterile Water for Inhalation is intended for use in all patient populations including adults, pediatrics, infants and neonates.	The predicate device and proposed device have the same indications for use
Prescription Use or OTC Use	Prescription Use	Prescription Use	Same
Single-Use	Yes	Yes	Same

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Design	The device is a flexible PP bottle prefilled with sterile water. It features a spikeable bromobutyl closure used to transfer the sterile water to humidifier chambers using tubular sets. The bottle includes an integrated hanger that is used to suspend the product during usage. Additionally, the device is available in a flexible pour PP bottle with a PP/PET aluminum induction seal and a PP screw cap, also prefilled with sterile water. The pour bottle is used to refill the sterile water in humidifier chambers.	The device is a flexible bottle made of LDPE. The bottle is prefilled with sterile water. It has a spikeable rubber disc that is used to transfer the sterile water to the humidifier chambers using tubular sets. It also has an integrated hanger that is used to suspend the product during usage.	Similar (SE#1)

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Model/Sizes	The models include three configurations of PP bottles: - 1000mL PP bottles with either a bromobutyl stopper and aluminium seal, or a PP/PET aluminium induction seal, PP screw cap, and tamper-evident plastic shrink wrap. - 500mL PP bottles with a PP/PET aluminium induction seal, PP screw cap, and tamper-evident plastic shrink wrap.	1000ml flexible bottle made of LDPE. The bottle is prefilled with same sterile water as the predicate. It has a spikeable rubber disc	Similar (SE#2)

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Mechanism of Action	Sterile Water for Inhalation, USP, is used to humidify air in respiratory therapy. It is transferred to a humidifier chamber where it is heated to produce water vapor. This vapor mixes with medical gases or air, ensuring the delivered air is moist. This prevents drying of the patient's airways, maintains mucous membrane moisture, enhances patient comfort and reduces the risk of respiratory complications.	The Sterile Water for Inhalation Flexoval® Bottle, is used to humidify air in respiratory therapy. It is transferred to a humidifier chamber where it is heated to produce water vapor. This vapor mixes with medical gases or air, ensuring the delivered air is moist. This process prevents the drying of the patient's airways, maintains mucous membrane moisture, enhances patient comfort, and reduces the risk of respiratory complications.	Same

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Biocompatibility	Meets the requirements of ISO 10993	Meets the requirements of ISO 10993	Same
Spike Access & Hanger	The 1000mL PP bottle with bromobutyl stopper and aluminum seal variant has Spike Access and Hanger	Universal Rubber Disc with 1 Standard Hanger	Similar (SE#3)
Container Clarity	Clear	Clear	Same
Chemical Composition	Sterile Water, USP	Sterile Water	Same
Packaging Material	Polypropylene	LDPE	Similar (SE#4)
Sterilization Method	Steam Air	Moist Heat	Same
Tamper Evidence	Yes	Yes	Same

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510 (k) SUMMARY	
STERILE WATER FOR INHALATION, USP	

Section	**Proposed Device** (Sterile Water for Inhalation, USP)	**Predicate Device** (Sterile Water for Inhalation in 1L Flexoval ® Bottles)	**Result**
Compounding	Water for the compounding is produced from drinking water that is purified in its final stage by distillation that demonstrates the elimination of chemicals, microorganisms and endotoxins and does not contain any added substances. Sterile water is filled in compounding tanks at 70°C and filled via bottle filling machine into bottles.	Water for the compounding is produced from drinking water that is purified in its final stage by distillation or other equivalent or superior technology that demonstrates the elimination of chemicals, microorganisms and endotoxins and does not contain any added substances. Sterile water is filled in compounding tanks at 70°C and filled via BFS into bottles.	Same

CONCLUSION

Based on the available information, Laboratorios Biogalenic, S.A. de C.V. concludes that Sterile Water for Inhalation, USP is substantially equivalent in terms of indications for use, design, and function to the existing legally marketed devices under the Federal Food, Drug, and Cosmetic Act. Therefore, the subject device is determined to be substantially equivalent to the predicate device.