March 6, 2025

Laboratorios Biogalenic S.A. DE C.V,
℅ Manoj Zacharias
US Agent
Liberty Management Group Ltd.
75 Executive Dr, Suite 114
Aurora, Illinois 60504

Re: K243001
Trade/Device Name: Sterile Water USP and Sterile 0.9% Normal Saline USP
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 7, 2025
Received: February 7, 2025

Dear Manoj Zacharias:

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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K243001

Device Name
Sterile Water USP and Sterile 0.9% Normal Saline USP

Indications for Use *(Describe)*

Over-the-Counter Use:
For moistening absorbent wound dressing and cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin.

Prescription Use:
For moistening absorbent wound dressing and for moistening, debriding, and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second-degree burns, cuts, abrasions, and minor skin irritations and for device irrigation.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) SUMMARY

[AS REQUIRED BY 21 CFR 807.92]

## I. SUBMITTER

| | | |
|---|---|---|
| **510(k) Owner's Name** | : | LABORATORIOS BIOGALENIC, S.A. DE C.V. |
| **Address** | : | Calle Claper, Blvd. Del Ejercito Nacional km 5.5, Soyapango, San Salvador, 1639 SV |
| **Telephone** | : | +503-2227-4133 |
| **Fax** | : | +503-2227-4466 |
| **Contact person** | : | Roberto Quiñonez |
| **Designation** | : | Plant Director |
| **Contact Number** | : | +503-2227-4133 EXT 106 |
| **Contact Email** | : | r.q@biogalenic.com.sv, biogal@biogalenic.com.sv |
| **Date of Summary Prepared** | : | 28.02.2025 |

## II. DEVICE

| | | |
|---|---|---|
| **Trade Name** | : | Sterile Water USP and Sterile 0.9% Normal Saline USP |
| **Device Common Name** | : | Sterile Water USP and Sterile 0.9% Normal Saline USP |
| **Device Classification Name** | : | Dressing, Wound, Drug |
| **Device Classification** | : | Unclassified |
| **Classification Panel** | : | General and Plastic Surgery |
| **Product Code** | : | FRO |

## III. PREDICATE DEVICE

| | | |
|---|---|---|
| **Predicate Device Name** | : | Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP |
| **510(k) Number** | : | K173276 |
| **Device Classification** | : | Unclassified |
| **Product Code** | : | FRO |

## IV. DEVICE DESCRIPTION

The subject device Sterile Water USP, and Sterile 0.9% Normal Saline USP is a colorless, transparent solution with no preservatives or antimicrobial agents added. It is used only for external irrigation, and not for injection purposes and it is a single use device. The subject device is packaged in clear, polypropylene (PP) bottles capped with PP Screw cap and filled with a sterile, preservative-free, clear, colorless aqueous solution and sealed with a PP/PET aluminum induction seal. The aqueous solution composition is either sterile water or sterile 0.9% normal saline, both which meet their respective USP monograph criteria and contain no additives. The container and closure system for the 250mL, 500mL, and 1000mL sizes include PP bottles with a PP screw cap with a PP/PET aluminum induction seal and a tamper evident plastic shrink wrap. The container and closure system for the 100mL size includes a PP bottle with a PP screw cap and a PP/PET aluminum induction seal.

These single-use devices are labeled for device irrigation and wound debridement and are not intended for injection. The subject device will function by the mechanical action associated with applying and moving an aqueous solution across a wound or device surface, which facilitates the moisturizing, debridement and irrigation of these surfaces.

Laboratorios Biogalenic Sterile Water USP and Sterile 0.9% Normal Saline USP are available in the following configurations:

| **Laboratorios Biogalenic Item Number** | **Description** |
|---|---|
| 78718-00060 | 100 mL Sterile Water, USP (OTC) |
| 78718-00061 | 250 mL Sterile Water, USP (OTC) |
| 78718-00062 | 500 mL Sterile Water, USP (OTC) |
| 78718-00063 | 1000 mL Sterile Water, USP (OTC) |
| 78718-00047 | 100 mL Sterile Water, USP (Prescription Use) |
| 78718-00048 | 250 mL Sterile Water, USP (Prescription Use) |
| 78718-00049 | 500 mL Sterile Water, USP (Prescription Use) |
| 78718-00050 | 1000 mL Sterile Water, USP (Prescription Use) |
| 78718-00065 | 100 mL Sterile 0.9% Normal Saline, USP (OTC) |
| 78718-00066 | 250 mL Sterile 0.9% Normal Saline, USP (OTC) |
| 78718-00067 | 500 mL Sterile 0.9% Normal Saline, USP (OTC) |
| 78718-00068 | 1000 mL Sterile 0.9% Normal Saline, USP (OTC) |
| 78718-00052 | 100 mL Sterile 0.9% Normal Saline, USP (Prescription Use) |
| 78718-00053 | 250 mL Sterile 0.9% Normal Saline, USP (Prescription Use) |
| 78718-00054 | 500 mL Sterile 0.9% Normal Saline, USP (Prescription Use) |
| 78718-00055 | 1000 mL Sterile 0.9% Normal Saline, USP (Prescription Use) |

## V. INDICATIONS FOR USE

**For Over-the-Counter Use**:

For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin.

**For Prescription Use**:

For moistening absorbent wound dressings and for moistening, debriding, and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second-degree burns, cuts, abrasions, and minor skin irritations and for device irrigation.

## VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Sterile Water USP, and Sterile 0.9% Normal Saline USP medical device contains a colorless, transparent solution without any preservatives or antimicrobial agents added. It is used only for external irrigation and wound debridement, not for injection purposes and it is a single use device. The solution's chemical composition is either sterile water or sterile saline (0.9% sodium chloride) which comply with their respective USP Monograph standards. The subject device is packaged in clear, polypropylene (PP) bottles capped with PP Screw cap and filled with a sterile, preservative-free, clear, colorless aqueous solution and sealed with a PP/PET aluminum induction seal.

## VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

**Table 1: General Comparison**

| Features compared | Proposed Device | Predicate Device | Result |
|---|---|---|---|
| Product Name | Sterile Water USP and Sterile 0.9% Normal Saline USP | Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP | NA |
| 510(k) Number | K243001 | K173276 | NA |
| Manufacturer | LABORATORIOS BIOGALENIC, S.A. DE C.V. | Medline Industries, Inc. | NA |
| Classification | Unclassified | Unclassified | Same |
| Product Code | FRO | FRO | Same |
| Prescription Use or OTC Use | Both | Both | Same |
| Contact duration | <24 hours | <24 hours | Same |

| Features compared | Proposed Device | Predicate Device | Result |
|---|---|---|---|
| Single-Use Vs. Reusable | Single use | Single use | Same |
| Indication For Use | **Over-the-Counter Use:**<br>For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin.<br><br>**Prescription Use:**<br>For moistening absorbent wound dressings and for moistening, debriding, and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second-degree burns, cuts, abrasions, and minor skin irritations and for device irrigation. | **Over-the-Counter Use:**<br>For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin.<br><br>**Prescription Use:**<br>For moistening absorbent wound dressings and for moistening, debriding, and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second-degree burns, cuts, abrasions, and minor skin irritations and for device irrigation. | Same |
| Technological Characteristics | Mechanical action associated with the application and movement of fluid (either Sterile Water or Saline) across a wound or device surface to facilitate the moisturizing, debridement, and irrigation of these surfaces. | Mechanical action associated with the application and movement of fluid (either Sterile Water or Saline) across a wound or device surface to facilitate the moisturizing, debridement, and irrigation of these surfaces. | Same |

<table>
<tr><th>Features compared</th><th colspan="2">Proposed Device</th><th colspan="2">Predicate Device</th><th>Result</th></tr>
<tr><td>Chemical Composition</td><td colspan="2">Sterile water USP or 0.9% Sterile normal saline USP, no antimicrobial or other substance added.</td><td colspan="2">Sterile Saline (0.9% Sodium Chloride) or Sterile Water for irrigation substantiated to meet USP; no antimicrobial or other substance added.</td><td>Same</td></tr>
<tr><td rowspan="3">Design Configuration</td><td>Content</td><td>Container</td><td>Content</td><td>Container</td><td rowspan="3">Similar</td></tr>
<tr><td>100 mL Sterile Water, USP<br>100 mL Sterile 0.9% Normal Saline, USP</td><td>PP bottle with a PP screw cap and a PP/PET aluminum induction seal</td><td rowspan="2">100 mL Sterile water, USP<br>250 mL Sterile water, USP<br>100 mL Normal Saline, USP<br>250 mL Normal Saline, USP<br>500 mL Sterile Water, USP<br>500 mL Normal Saline, USP</td><td rowspan="2">HDPE Bottles made from polyethylene (PE) resin. Include an induction-heat seal and liner with a polypropylene (PP) screw cap closure</td></tr>
<tr><td>250 mL Sterile Water, USP<br>500 mL Sterile Water, USP<br>1000 mL Sterile Water, USP<br>250 mL Sterile 0.9% Normal Saline, USP<br>500 mL Sterile 0.9% Normal Saline, USP<br>1000 mL Sterile 0.9% Normal Saline, USP</td><td>PP bottles with a PP screw cap with a PP/PET aluminum induction seal and a tamper evident plastic shrink wrap</td></tr>
</table>

| Features compared | Proposed Device | Predicate Device | Result |
|---|---|---|---|
| Performance Specifications | The sterile water USP and sterile 0.9% normal saline USP is manufactured from respective Water for Injection and Sodium Chloride for injection that is designed, tested and operated in accordance with the USP monographs: Water for injection USP and Sodium Chloride USP. | The sterile water and sterile saline is manufactured from Water for Irrigation that is designed, tested and operated in accordance with the USP monograph for Water for Irrigation, as specified in USP General Chapter: Water for Pharmaceutical Purposes <1231> | Similar |
| Material of packaging | PP Bottles | HDPE | Different |
| Sterilization | Terminal (STEAM) | Gamma Sterilization | Different |
| Shelf Life | 2 Years | 1 Year | Different |

## VIII. PERFORMANCE TESTING DATA

### A. Biocompatibility Testing

The biocompatibility evaluation of the Sterile Water USP and Sterile 0.9% Normal Saline USP was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. The results of the evaluation, based on the tests outlined below, confirmed that the devices are biocompatible:

- In Vitro Cytotoxicity (L929 Cell Line) conducted as per ISO 10993-5:2009, Third Edition: Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity
- Intracutaneous Reactivity conducted as per ISO 10993-23:2021, First Edition: Biological Evaluation of Medical Devices: Tests for Irritation
- Skin Sensitization (Guinea Pig Maximization Test) conducted as per ISO 10993-10:2021 Fourth Edition: Biological Evaluation of Medical Devices: Tests for Skin Sensitization
- Acute Systemic Toxicity (in Swiss Albino Mice) conducted as per ISO 10993-11:2017: Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- Material Mediated Pyrogenicity test (in New Zealand white rabbits) conducted as per ISO 10993-11:2017: Biological evaluation of medical devices- Part 11: Tests for systemic toxicity

### B. Packaging and Transportation Testing

Packaging and transportation tests have been conducted to demonstrate that the complete packaging system used for Sterile Water, USP, and Sterile 0.9% Normal Saline, USP meets the

required standards of effectiveness and quality. The Sterile water, USP and Sterile 0.9% Normal Saline, USP complies with the criteria for each test provided below, ensuring the product is safe for use:

- **Visual inspection of seal (ANSI Z 1.4)-** no defects identified.
- **Dye Migration Test (ASTM F1929-23)-** no bottles exhibited leakage or deformation.
- **Determination of leaks in flexible packaging by bubble emission (ASTM D3078-02)-** No leakage detected and no variation in weight observed.
- **Internal Pressurization failure resistance of unrestrained packages (ASTM F1140)-** no leakage observed.
- **Drop Test of Loaded Containers by Free fall (ASTM D5276-19)-** Containers remained undamaged after the fall.
- **Box compression Test (ASTM D642)-** successfully withstood the maximum weight stack.

## C. Non- Clinical Performance Testing (Bench)

Sterile Water USP and Sterile 0.9% Normal Saline USP have been demonstrated to be both effective and safe for their intended purposes, as supported by the results of the non-clinical performance evaluations outlined below:

**Sterile Water USP**

- Total organic carbon USP <643>
- Water Conductivity USP <643>
- Sterility Test USP <71>
- Bacterial endotoxins Test USP <85>
- Appearance
- Volume in Container

**Sterile 0.9% Normal Saline USP**

- Sodium Chloride Titration USP Monograph
- Identification USP <191>
- pH USP <791>
- Iron USP <241>
- Volume in Container
- Appearance
- Sterility Test USP <71>
- Bacterial Endotoxins Test USP <85>

## D. Clinical Test Data

No clinical study was conducted since clinical data is not necessary for Sterile Water USP and Sterile 0.9% Normal Saline USP.

## IX. CONCLUSION

Based on testing and comparison to the predicate device, Sterile Water USP and Sterile 0.9% Normal Saline USP for Irrigation are as safe and effective for their intended use as the predicate, Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP.