



Medline Industries, Inc.  
Claire Pigman  
Senior Regulatory Affairs Specialist  
Three Lakes Drive  
Northfield, Illinois 60093

Re: K173276

Trade/Device Name: Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: June 1, 2018  
Received: June 5, 2018

Dear Claire Pigman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden

-S

Digitally signed by Neil R Ogden -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Neil R Ogden -S,  
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Date: 2018.07.02 13:58:30 -04'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173276

Device Name

Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP

Indications for Use (Describe)

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.

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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Medline Industries, Inc.  
Three Lakes Drive  
Northfield, IL 60093

K173276

## **SECTION 5**

### **510(k) SUMMARY**

### **[AS REQUIRED BY 21CFR807.92(c)]**

#### **Submitter / 510(k) Sponsor**

Medline Industries, Inc.  
Three Lakes Drive  
Northfield, IL 60093  
Registration Number: 1417592

#### **Contact Person**

Claire Pigman  
Sr. Regulatory Affairs Specialist  
Phone: 847-643-4071  
Email: [cpigman@medline.com](mailto:cpigman@medline.com)

#### **Summary Preparation Date**

October 9, 2017

#### **Type of 510(k) Submission**

Traditional

#### **Device Name / Classification**

Name of Device: Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP  
Device Common Name: Sterile Water and Sterile Saline  
Classification Name: Dressing, Wound, Drug  
Product Code: FRO  
Classification Panel: General and Plastic Surgery Devices  
Device Classification: Unclassified  
Regulation Number: Pre-Amendment

#### **Predicate Device**

Predicate Device Name: Wound Flush, Sterile Water and Sterile Normal Saline  
Predicate Device Sponsor: Nurse Assist, Inc.  
Predicate Device K Number: K083042

#### **Device Description**

The subject devices are 100 mL, 250 mL or 500 mL sterile water or sterile normal saline (0.9% Sodium Chloride). The design of these single-use devices incorporates clear, high density polyethylene (HDPE)



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bottles filled and sealed with a sterile, preservative-free, clear, colorless, aqueous solution, as labeled for device irrigation and wound debridement (not for injection). The subject device will function by means of mechanical action; specifically, by the mechanical mechanism of 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.

The chemical composition of its aqueous solution is either sterile water or sterile saline (0.9% Sodium Chloride in sterile water) for irrigation, which have been substantiated to each meet their respective USP monograph criteria, and its formulation contains no additives. The components of the subject device's container and closure system, made from polyethylene (PE) resins and an induction-heat seal and liner, meet the requirements of the Agency's food additive regulations. Medline Sterile Water USP and Sterile 0.9% Normal Saline USP are available in the following configurations:

| Medline Item Number | Description                                      |
|---------------------|--------------------------------------------------|
| RDI30295            | Medline Sterile Water, USP - 100 mL              |
| PCS1550             | Medline Sterile Water, USP - 250 mL              |
| DYND500MLW          | Medline Sterile Water, USP - 500 mL              |
| RDI30296            | Medline Sterile 0.9% Normal Saline, USP - 100 mL |
| PCS1650             | Medline Sterile 0.9% Normal Saline, USP - 250 mL |
| DYND500MLS          | Medline Sterile 0.9% Normal Saline, USP - 500 mL |

Please note that all six of these configurations are designed to consist of either sterile water USP or sterile normal saline (0.9% Sodium Chloride) USP, packaged and sealed in HDPE bottles and terminally sterilized using gamma irradiation. Please refer to Section 11 of this Premarket Notification for a more comprehensive description of this device.

### 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.

### Summary of Technological Characteristics

Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP are single-use devices and their design incorporates clear, high density polyethylene (HDPE) bottles filled and sealed with a sterile, preservative-free, clear, colorless, aqueous solution, as labeled for device irrigation and wound debridement (not for injection). The chemical composition of its aqueous solution is either sterile water



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or sterile saline (0.9% Sodium Chloride) for irrigation, which have been substantiated to each meet their respective USP monograph criteria, and its formulation contains no additives.

In addition, the subject device is similar in design, intended use and function to the predicate device, Nurse Assist Wound Flush, Sterile Water and Sterile Normal Saline, cleared under K083042. The table below provides a side-by-side comparison of the proposed and predicate devices. Please refer to Section 12 for a further discussion of the similarities and differences between the two devices.

**Table 1: Comparison of Proposed and Predicate Devices**

| Device Characteristic          | Proposed Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                      | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                        | Comparison Analysis |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Product Name                   | Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                      | Nurse Assist Wound Flush, Sterile Water and Sterile Normal Saline                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                        | N/A                 |
| 510(k) Reference               | K173276                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                      | K083042                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                        | N/A                 |
| Product Owner                  | Medline Industries, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                      | Nurse Assist Incorporated                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                        | N/A                 |
| Product Code                   | FRO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                      | FRO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                        | Same                |
| Indication for Use             | Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin<br><br>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. |                                                                                                                                      | Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.<br><br>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. |                                                                                                                                        | Same                |
| Regulation Number              | Pre-Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                      | Pre-Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                        | Same                |
| Technological Characteristics: | Principle mechanism of action is through the 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 of fluid moving across the wound or device provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris.                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                        | Same                |
| Chemical Composition           | Sterile Saline (0.9% Sodium Chloride) or Sterile Water for irrigation substantiated to meet USP; no antimicrobial or other substance added.                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                      | Sterile Saline (0.9% Sodium Chloride) or Sterile Water for irrigation substantiated to meet USP; no antimicrobial or other substance added.                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                        | Same                |
| Design Configurations          | CONTENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | CONTAINER                                                                                                                            | CONTENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | CONTAINER                                                                                                                              | Similar             |
|                                | 100 mL Sterile Water, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | HDPE Bottles made from polyethylene (PE) resin. Include an induction-heat seal and liner with a polypropylene (PP) screw cap closure | 100 mL USP Sterile Water                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HDPE Bottles made from polyethylene (PE) resin. Include an induction sealed inner pull tab with a polypropylene (PP) screw cap closure |                     |
|                                | 250 mL Sterile Water, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                      | 250 mL USP Sterile Water                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                        |                     |
|                                | 100 mL Normal Saline, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                      | 100 mL USP Normal Saline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                        |                     |
|                                | 250 mL Normal Saline, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                      | 250 mL USP Normal Saline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                        |                     |
|                                | 500 mL Sterile Water, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                        |                     |
|                                | 500 mL Normal Saline, USP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                        |                     |
|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                      | 120 mL USP Sterile Water                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | White polypropylene (PP) cup with heat sealed foil lid                                                                                 |                     |
|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                      | 120 mL USP Normal Saline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                        |                     |
|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                      | 210 mL USP Normal Saline                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                        |                     |
| Performance Specifications     | 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: <i>Water for Pharmaceutical Purposes</i> <1231>                                                                                                                                                                                                                                                    |                                                                                                                                      | 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: <i>Water for Pharmaceutical Purposes</i> <1231>                                                                                                                                                                                                                                                     |                                                                                                                                        | Same                |

**Table 1: Comparison of Proposed and Predicate Devices**

| <b>Device Characteristic</b>         | <b>Proposed Device</b>     | <b>Predicate Device</b>    | <b>Comparison Analysis</b> |
|--------------------------------------|----------------------------|----------------------------|----------------------------|
| <b>Prescription vs. OTC</b>          | Prescription Use & OTC Use | Prescription Use & OTC Use | Similar                    |
| <b>Contact Durations</b>             | <24 hours                  | <24 hours                  | Same                       |
| <b>Sterile vs. Non-Sterile</b>       | Sterile                    | Sterile                    | Same                       |
| <b>Sterilization Method</b>          | Gamma Radiation            | Gamma Radiation            | Same                       |
| <b>Disposable vs. Non-Disposable</b> | Disposable                 | Disposable                 | Same                       |
| <b>Single Use vs. Reusable</b>       | Single Use                 | Single Use                 | Same                       |
| <b>Shelf Life</b>                    | 1 year                     | 2 years                    | Different                  |



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### Shelf Life and Sterilization

Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP are sterilized by gamma radiation and its sterilization validation has been conducted in accordance with AAMI TIR33, Sterilization of healthcare products – Radiation – Substantiation of a selected sterilization dose – Method V<sub>Dmax</sub> to ensure that the determined minimum irradiation dose achieves a Sterility Assurance Level (SAL) of 10<sup>-6</sup>.

Additionally, in accordance with ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, aging studies have been conducted to verify the shelf life of the subject device and ensure its sterility is successfully maintained throughout its shelf life.

### Summary of Non-Clinical Testing

Non-clinical verification of Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP has been conducted to evaluate its safety, performance and functionality. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination.

The biocompatibility evaluation for the Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP was conducted in accordance with ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The proposed device is classified as a surface device with a limited duration of contact (<24 hours) on potentially breached or compromised surfaces. Based on this classification, the following tests were performed to evaluate the biocompatibility of the Medline Sterile Water USP and Sterile 0.9% Normal Saline USP:

- ISO 10993-5: 2009 Biological evaluation of medical devices- Part 5: Tests for *in vitro* cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test Procedure, Material-Mediated Rabbit Pyrogen Testing



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### **Performance Testing (Bench)**

Non-clinical verification of Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP has been conducted to evaluate the safety, performance and functionality of the proposed device. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination.

### **Summary of Clinical Testing**

Not applicable. No clinical testing was done on the proposed device.

### **Conclusion**

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Sterile Water USP and Medline Sterile 0.9% Normal Saline USP are as safe and as effective for their intended use as the predicate device Nurse Assist Wound Flush, Sterile Water and Sterile Normal Saline (K083042).