February 20, 2026

BD
Dainel Ehrhardt
Senior Specialist, Regulatory Affairs
75 N Fairway Dr.
Vernon Hills, Illinois 60061

Re: K253445
Trade/Device Name: BD Surgiphor™ 1000 mL Antimicrobial Irrigation System (910120)
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH; FRO
Dated: October 1, 2025
Received: November 13, 2025

Dear Dainel Ehrhardt:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Yu-chieh Chiu -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253445

Device Name
BD Surgiphor™ 1000 mL Antimicrobial Irrigation System (910120)

Indications for Use *(Describe)*
BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Preparation Date:	October 1, 2025
510(k) Number:	K253445
Applicant:	Becton, Dickinson and Company 75 N Fairway Dr Vernon Hills, IL 60061
Contact Person:	Daniel Ehrhardt Senior Specialist, Regulatory Affairs, Tel: (303) 217-1876
Device Trade Name:	BD Surgiphor™ 1000 mL Antimicrobial Irrigation System
Classification Name:	Jet Lavage
Device Classification:	Class II (21 CFR 880.5475) Unclassified (Pre-amendment)
Product Code:	FQH; FRO
Predicate Device:	BD Surgiphor™ Antimicrobial Irrigation System Product Code: FQH (Jet Lavage), FRO (Dressing, Wound, Drug); Class II (21 CFR 880.5475) Applicant: Becton, Dickinson and Company (BD) K221504

Device Description

The subject BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is a terminally sterilized 1000 mL aqueous solution for irrigation and debridement of wounds. The device includes one bottle of Surgiphor™ solution (0.5% povidone-iodine) which is used to loosen and remove wound debris via manual lavage or a powered lavage device. Components are included with the bottle in the system tray to support each lavage type; one screw cap for manual irrigation and one adaptor and one Y-connector for powered irrigation. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the loosening and removal of debris, and foreign materials, including microorganisms, from wounds. The povidone-iodine in the Surgiphor™ solution serves as a preservative to ensure that no microbial growth occurs in the solution after the bottle is open.

Indications for Use

BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds.

Comparison of Technological Characteristics

The subject device is substantially equivalent to its predicate, predecessor BD Surgiphor™ Antimicrobial Irrigation System (K221504). Table 1 compares the subject and predicate devices.

The subject device is unchanged from the legally marketed predicate BD Surgiphor™ Antimicrobial Irrigation System (K221504) in its intended use, solution composition, and primary mechanism of action, specifically, to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds. The mechanism of action is defined by the fluid pressure of the solution dispensed upon a wound.

This 510(k) proposes a new configuration of the Surgiphor solution in a 1000 mL bottle with components to allow for use with a powered lavage device. A powered lavage device is not included with the subject device as they are readily available to users. The instructions for use of the subject device instructs users to use either a manual lavage configuration, similar to the predicate device Surgiphor™ (K221504), or a powered lavage configuration. The powered lavage configuration allow users to connect the 1000 mL bottle by spiking the adaptor directly or using the optional Y-connector to dispense the Surgiphor solution through a powered lavage device. The Surgiphor solution remains unchanged 0.5% povidone-iodine (PVP-I) in phosphate-buffered saline with potassium iodide and Vitamin E TPGS from the predicate device. Due to the new configuration, a new packaging was designed to accommodate the additional components and bottle size. The labeling has been designed to instruct the users on how to use the subject device in either configuration, manual or powered.

With the manual screw cap and Surgiphor solution remaining unchanged from the predicate device, the previously provided testing in K221504 and previous 510(k)s remains valid. For the subject device, there is no change to the intended use, and the change does not raise new safety and effectiveness concerns. Substantial equivalence has been demonstrated through conformity to standards and design verification and validation testing.

Table 1 – Comparison of Subject and Predicate Devices

Comparison Feature	Subject Device: BD Surgiphor™ 1000 mL Antimicrobial Irrigation System	Predicate Device: BD Surgiphor™ Antimicrobial Irrigation System
510(K) Number	K253445	K221504
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FQH, Jet Lavage FRO, Dressing, Wound, Drug
Product Classification	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)
Device Description	BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is an antimicrobial irrigation system containing 0.5% povidone-iodine (PVP-I) in phosphate-buffered saline, potassium iodide and Vitamin E TPGS with additional components for manual and powered irrigation. PVP-I acts as a preservative to help inhibit microbial growth in the irrigation solution.	BD Surgiphor™ Antimicrobial Irrigation System is an antimicrobial irrigation system containing 0.5% povidone-iodine (PVP-I) in phosphate-buffered saline, potassium iodide and Vitamin E TPGS. PVP-I acts as a preservative to help inhibit microbial growth in the irrigation solution.
Intended Use	Intended for wound cleansing and removal of wound debris	Intended for wound cleansing and removal of wound debris
Indications For Use	BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds.	BD Surgiphor™ Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds.
Type of Use	Prescription use only	Prescription use only
Mechanism of Action	The mechanical action of fluid across the wound removes wound debris, including microorganisms. The mechanical action of the irrigation can be by manual or powered irrigation.	The mechanical action of fluid across the wound removes wound debris, including microorganisms.
Solution	Surgiphor solution (0.5% povidone-iodine plus vitamin E TPGS in 0.9% saline)	Surgiphor solution (0.5% povidone-iodine plus vitamin E TPGS in 0.9% saline)
Solution Antimicrobial Preservative	0.5% povidone-iodine	0.5% povidone-iodine
How Supplied	1 – 1000 mL Surgiphor solution (0.5% povidone-iodine plus vitamin E TPGS in 0.9% saline); pH 4.6 – 7.0 1 – Manual Screw Cap 1 – Powered Lavage Adaptor 1 – Y-connector Packed within a HDPE heat-sealed tray with a Tyvek cover and sterilized by gamma irradiation to achieve a SAL of 10^{-6}. Instructions for Use are included with the system.	1 – 450 mL Surgiphor solution (0.5% povidone-iodine plus vitamin E TPGS in 0.9% saline); pH 4.6 – 7.0 1 – Manual Screw Cap Packed within a PETG heat-sealed tray with a Tyvek cover and sterilized by gamma irradiation to achieve a SAL of 10^{-6}. Instructions for Use are included with the system.
Storage Conditions	Store at room temperature. Avoid freezing or heating above 40°C (104°F).	Store at room temperature. Avoid freezing or heating above 40°C (104°F).

Comparison Feature	Subject Device: BD Surgiphor™ 1000 mL Antimicrobial Irrigation System	Predicate Device: BD Surgiphor™ Antimicrobial Irrigation System
Applicator	Manual screw cap with spike threads onto the 1000 mL bottle. The user squeezes the bottle to dispense the solution onto the wound. Adaptor with spike threads onto the 1000 mL bottle. The user connects a powered irrigation device to the bottle to dispense irrigation solution onto the wound. Optionally, the user can use the provided Y-connector to connect the adaptor on the bottle to a powered lavage device for convenient switching between the Surgiphor solution and saline (not provided) for rinsing.	Polycarbonate cap with spike threads onto the polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.

Standards and Testing

The following tests were conducted to support the changes under this traditional 510(k):

- Biocompatibility
  - ISO 10993-1: 2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- Endotoxin and Pyrogens
  - USP General Chapter <85> *Bacterial Endotoxins Test*
  - (AAMI) ST72: 2019/R2010 *Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing, Includes Erratum*
- Sterilization
  - ANSI/AAMI/ISO TIR13004:2022, *Sterilization of Health Care Products - Radiation - Substantiation of a Selected Sterilization Dose: Method VDmaxSD*
  - ANSI/AAMI/ISO 11137-1:2006/ (R) 2015 & A1:2013 & A2:2019, *Sterilization of Health Care Products — Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
  - ANSI/AAMI/ISO 11137-2:2013/ (R) 2019, *Sterilization of Health Care Products — Radiation – Part 2: Establishing the sterilization dose*
  - ANSI/AAMI/ISO 11737-1:2018: *Sterilization of Health Care Products — Microbiological methods – Part 1: Determination of the population of microorganisms on product*
  - ANSI/AAMI/ISO 11137-3: 2017 *Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine*
- Packaging and Shelf-Life
  - ISO 11607-1: 2019 *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
  - ISO 11607-2: 2019 *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
  - ISO/TS 16775: 2014 *Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2*
  - ASTM F1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
  - ASTM F2096-11, *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*
  - ASTM D4169-16, *Standard Practice for Performance Testing of Shipping Containers and Systems*
  - ASTM F2825-18: *Standard Practice for Climatic Stressing of Packaging System for Single Parcel Delivery*
  - ASTM F88-09: 2009 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- Functional Testing
  - ISO 18250-1:2018 *Medical devices- Connectors for reservoir delivery systems for healthcare applications – Part 1: General requirements and common test methods*
  - Customized tests to demonstrate mechanical action to loosen and remove wound debris/foreign materials

Substantial Equivalence Conclusion

The subject BD Surgiphor™ 1000 mL Antimicrobial Irrigation System is substantially equivalent to the previously cleared BD Surgiphor™ Antimicrobial Irrigation System (K221504) with the changes described within this submission. The changes do not impact the safety or effectiveness of the subject device.