February 25, 2026

Becton, Dickinson and Company (BD)
Daniel Ehrhardt
Staff Regulatory Affairs Specialist
75 N Fairway Dr.
Vernon Hills, Illinois 60061

Re: K253996
Trade/Device Name: BD Surgiphor™ Antimicrobial Irrigation System (910110)
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage; Wound dressing, drug
Regulatory Class: Class II; Unclassified
Product Code: FQH; FRO
Dated: January 26, 2026
Received: January 26, 2026

Dear Daniel 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253996

Device Name
BD Surgiphor™ Antimicrobial Irrigation System

Indications for Use *(Describe)*
BD Surgiphor™ 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.

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510(k) Summary

Preparation Date:	December 12, 2025
510(k) Number:	K253996
Applicant:	Becton, Dickinson and Company 75 N Fairway Dr Vernon Hills, IL 60061
Contact Person:	Daniel Ehrhardt Staff Regulatory Affairs Specialist Tel: (303) 217-1876
Device Trade Name:	BD Surgiphor™ 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™ Antimicrobial Irrigation System is a terminally sterilized 450 mL aqueous solution for irrigation and debridement of wounds. The device includes one screw cap and one bottle of Surgiphor solution (0.5% povidone-iodine (PVP-I)), which is used to loosen and remove wound debris via manual lavage. 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 PVP-I 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™ 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 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, packaging, and design, except for the material of the bottle itself. The mechanism of action to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds, is unchanged as well. The mechanism of action is defined by the fluid pressure of the solution dispensed upon a wound.

This 510(k) proposes a new material for the 450mL bottle containing the Surgiphor solution. The bottle material of the predicate is polypropylene and the proposed bottle material for the subject device is high-density polyethylene (HDPE). There are no changes to the screw cap, packaging, nor other design aspects, including the bottle shape and dimensions. The Instructions for Use of the subject device are identical to the predicate device. The Surgiphor solution remains unchanged from the predicate device, as a dilute PVP-I solution containing 0.5% PVP-I in phosphate-buffered saline with potassium iodide and vitamin E TPGS.

With the packaging, 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™ Antimicrobial Irrigation System	Predicate Device: BD Surgiphor™ Antimicrobial Irrigation System	Subject to Predicate Comparison
510(K) Number	K253996	K221504	N/A
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FQH, Jet Lavage FRO, Dressing, Wound, Drug	Identical to predicate
Product Classification	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)	Identical to predicate
Device Description	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.	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.	Identical to predicate
Intended Use	Intended for wound cleansing and removal of wound debris	Intended for wound cleansing and removal of wound debris	Identical to predicate
Indications For Use	BD Surgiphor™ 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.	Identical to predicate
Type of Use	Prescription use only	Prescription use only	Identical to predicate
Mechanism of Action	The mechanical action of fluid across the wound removes wound debris, including microorganisms.	The mechanical action of fluid across the wound removes wound debris, including microorganisms.	Identical to predicate
Solution	Surgiphor solution (0.5% PVP-I plus vitamin E TPGS in 0.9% saline)	Surgiphor solution (0.5% PVP-I plus vitamin E TPGS in 0.9% saline)	Identical to predicate
Solution Antimicrobial Preservative	0.5% PVP-I	0.5% PVP-I	Identical to predicate

Comparison Feature	Subject Device: BD Surgiphor™ Antimicrobial Irrigation System	Predicate Device: BD Surgiphor™ Antimicrobial Irrigation System	Subject to Predicate Comparison
How Supplied	1 – 450 mL Surgiphor solution (0.5% PVP-I 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.	1 – 450 mL Surgiphor solution (0.5% PVP-I 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.	Identical to predicate
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).	Identical to predicate
Applicator	Polycarbonate cap with spike threads onto the high-density polyethylene (HDPE) bottle. The user squeezes the bottle to dispense the solution onto the wound.	Polycarbonate cap with spike threads onto the polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.	The material for the bottle containing Surgiphor solution is changed to HDPE from polypropylene.

Standards and Testing

The following tests were conducted to support the changes under this 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
  - AANSI/AAMI/ISO 13004:2022, *Sterilization of Health Care Products – Radiation – Substantiation of selected sterilization dose: Method VDmax^{SD}*
  - ANSI/AAMI/ISO 11737-1:2018, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*
  - ANSI/AAMI/ISO 11737-2:2019, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
- Functional Testing
  - Customized tests to demonstrate mechanical action to loosen and remove wound debris/foreign materials

Substantial Equivalence Conclusion

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