October 14, 2022

BD
Shelley Wilcox
Staff Regulatory Affairs Specialist
75 N Fairway Dr
Vernon Hills, Illinois 60061

Re: K221504
Trade/Device Name: BD Surgiphor™ Antimicrobial Irrigation System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage; Wound dressing, drug
Regulatory Class: Class II; Unclassified
Product Code: FQH; FRO
Dated: August 30, 2022
Received: August 31, 2022

Dear Shelley Wilcox:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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.

Submission Number *(if known)*

K221504

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:	October 14, 2022
510(k) Number:	K221504
Applicant:	Becton, Dickinson and Company 75 N Fairway Dr Vernon Hills, IL 60061
Contact Person:	Shelley Wilcox Staff Specialist, Regulatory Affairs, Tel: (303) 324-3816
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) K213616

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 bottle of Surgiphor™ solution (0.5% Povidone Iodine) which is used to loosen and remove wound debris. 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 unwanted 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 BD Surgiphor™ Antimicrobial Irrigation System is substantially equivalent to its predicate, predecessor BD Surgiphor™ Antimicrobial Irrigation System (K213616).

The BD Surgiphor™ Antimicrobial Irrigation System is unchanged from the legally marketed predicate BD Surgiphor™ Antimicrobial Irrigation System (K213616) in its intended use, performance, and technological characteristics, 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 to remove the bottle of SurgiRinse™ solution from the predicate two bottle system as sterile saline solutions are readily available for use. Users are still instructed to use sterile saline to rinse the Surgiphor™ solution immediately after irrigation. As such the subject BD Surgiphor™ Antimicrobial Irrigation System comprises of only one bottle of Surgiphor™ solution containing 0.5% povidone iodine (PVP-I) in phosphate-buffered saline, potassium iodide and Vitamin E TPGS. There is no change to the solution composition from the predicate to the subject Surgiphor™ solution. This difference results in a change to the packaging size and the labeling content. The packaging utilizes the same materials of construction.

The only difference between the subject and the predicate is the removal of the SurgiRinse™ solution. There is no change to the intended use of the device and the change does not raise new safety and effectiveness concerns. Substantial equivalence has been demonstrated through standards compliance and design verification and validation testing.

Table 1: **Comparison of Subject Device and Predicate Device**

Comparison Feature	**Subject Device:** **BD Surgiphor™ Antimicrobial Irrigation System**	**Predicate Device:** **BD Surgiphor™ Antimicrobial Irrigation System**
510(K) Number	K221504	K213616
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-Amendments)	Class II (21 CFR 880.5475) Unclassified (Pre-Amendments)
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 a system of two sterile irrigation solutions. BD Surgiphor™ solution (0.5% povidone iodine (PVP-I) in phosphate-buffered saline, potassium iodide and Vitamin E TPGS) is used to mechanically loosen and remove wound debris and BD SurgiRinse™ solution (0.9% saline) is used to rinse wounds. 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™ 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 fluid across the wound removes wound debris, including microorganisms.
Solution	1 bottle of Surgiphor solution (0.5% povidone iodine plus vitamin E TPGS in 0.9% saline)	1 bottle of Surgiphor solution (0.5% povidone iodine plus vitamin E TPGS in 0.9% saline) 1 bottle of SurgiRinse solution (sterile saline, USP)
Solution Antimicrobial Preservative	0.5% povidone iodine	0.5% povidone iodine
How Supplied	1 – 450 mL Surgiphor solution (0.5% povidone iodine plus vitamin E TPGS in 0.9% saline); pH 4.6 – 7.0; Packed within a PETG tray heat-sealed with a Tyvek® cover, and sterilized by gamma irradiation to achieve a SAL of 10^{-6}. IFU are included with the system.	1 – 450 mL bottle of Surgiphor solution (0.5% povidone iodine plus vitamin E TPGS in 0.9% saline); pH 4.6 – 7.0; 1 – 450 mL bottle of sterile saline, USP; Packed within a PETG tray heat-sealed with a Tyvek® cover, and sterilized by gamma irradiation to achieve a SAL of 10^{-6}. IFU 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).
Applicator	Polycarbonate cap with a spike threads onto a polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.	Polycarbonate cap with a spike threads onto a polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.

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

- Sterilization
  - ANSI/AAMI/ISO TIR13004:2015, *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*
- Packaging and Shelf-Life
  - ISO 11607-1, *Packaging for Terminally Sterilized Medical Devices*
  - ASTM F1980-16, *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*

Substantial Equivalence Conclusion

The subject BD Surgiphor™ Antimicrobial Irrigation System is substantially equivalent to the previously cleared BD Surgiphor™ Antimicrobial Irrigation System (K213616) with the changes described within this submission. The changes do not impact the safety or effectiveness of the subject device.