March 23, 2022

Becton, Dickinson and Company
Shelley Wilcox
Staff Regulatory Affairs Specialist
75 N Fairway Dr
Vernon Hills, Illinois 60061

Re: K213616
Trade/Device Name: BD Surgiphor Antimicrobial Irrigation System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH, FRO
Dated: February 15, 2022
Received: February 16, 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
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)*

K213616

Device Name

BD Surgiphor™ Antimicrobial Irrigation System (910100)

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.

510(k) SUMMARY

Preparation Date:	22 MAR 2021
510(k) Number:	K213616
Applicant:	BD 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
Primary Predicate Device:	Irrisept® Antimicrobial Wound Lavage Product System Product Code: FQH (Jet Lavage); Class II (21 CFR 880.5475) Product Code FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) Applicant: Irrimax Corporation K210536
Secondary Predicate Device:	Surgiphor™ Wound Irrigation System Product Code: FQH (Jet Lavage); Class II (21 CFR 880.5475) Applicant: Orthophor LLC K202071
Reference Device:	Atteris Antimicrobial Skin and Wound Cleanser Product Code: FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) Applicant: Rochal Industries, LLC K160192

Device Description:
The BD Surgiphor™ Antimicrobial Irrigation System is a 2-step system of aqueous solutions for irrigation and debridement of wounds. The 2-step process includes one bottle of Surgiphor™ Solution (0.5% Povidone Iodine) which is used first to loosen wound debris, and one bottle of SurgiRinse™ Solution (saline solution, USP 99.95%) which is used second to rinse the loosened debris from the wound. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, and foreign materials, including microorganisms, from wounds. The BD Surgiphor™ Antimicrobial Irrigation System is provided as a two-part terminally sterilized system with 450 mL of each solution. 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 secondary predicate, predecessor Surgiphor Wound Irrigation System (K202071), primary predicate Irrisept® Antimicrobial Wound Lavage (K210536) and reference device, Atteris Antimicrobial Skin and Wound Cleanser (K160192).

The Surgiphor solution comprises 0.5% povidone iodine in sterile saline while the Irrisept solution comprises 0.05% chlorhexidine gluconate and the Atteris solution, polyaminopropyl biguanide (PHMB) in purified water. The composition of all three solutions acts as a preservative to inhibit microbial growth in the respective solutions.

The mechanism of action is the same between the proposed and the predicates, specifically, the mechanical action of fluid across the wound removes wound debris, including microorganisms. The mechanism of action is defined by the fluid pressure of the solution, dispensed upon a wound, which is demonstrated by testing provided in this 510(k).

The BD Surgiphor™ Antimicrobial Irrigation System is unchanged from the legally marketed predicate Surgiphor™ Wound Irrigation System (K202071) in its intended use, performance, and technological characteristics except as noted in subsequent comparison of technological characteristics table. The removal of wound debris and foreign materials, including microorganisms, is consistent with the primary predicate Irrisept® Antimicrobial Wound Lavage (K210536) and reference predicate device Atteris Antimicrobial Skin & Wound Cleanser (K160192). All three predicate devices have the same intended use and apply a solution to the wound for removal of wound debris and foreign materials, including microorganisms.

This 510(k) is to specify the removal of microorganisms through mechanical cleansing action within the indications for use statement of the BD Surgiphor™ Antimicrobial Irrigation System consistent with predicates Irrisept Antimicrobial Wound Lavage and the Atteris Antimicrobial Skin & Wound Cleanser.

Comparison of Technological Characteristics				
Comparison Feature	**Proposed Device** **BD Surgiphor™ Antimicrobial Irrigation System**	**Primary Predicate Device** **Irrisept® Antimicrobial Wound Lavage**	**Secondary Predicate Device** **Surgiphor™ Wound Irrigation System**	**Reference Device** **Atteris Antimicrobial Skin & Wound Cleanser**
510(K) Number	TBD	K210536	K202071	K160192
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	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)	Class II (21 CFR 880.5475)	Unclassified (Pre-Amendment)
Intended Use	Intended for wound cleansing and removal of wound debris	Intended for wound cleansing and removal of wound debris	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.	Irrisept® Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.	The Surgiphor™ Wound Irrigation System is a wound cleansing delivery system intended to loosen and remove wound debris.	(Rx Use) Atteris Antimicrobial Skin & Wound Cleanser is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first and second-degree burns, grafted and donor sites. (OTC Use) Atteris Antimicrobial Skin & Wound Cleanser is intended for physical cleaning and removal of dirt and debris, from skin scrapes, cuts, lacerations, minor irritations, exit sites and unbroken skin.
Type Of Use	Prescription use only	Prescription use only	Prescription use only	Both prescription use and over-the-counter use

Comparison of Technological Characteristics				
Comparison Feature	**Proposed Device** **BD Surgiphor™ Antimicrobial Irrigation System**	**Primary Predicate Device** **Irrisept® Antimicrobial Wound Lavage**	**Secondary Predicate Device** **Surgiphor™ Wound Irrigation System**	**Reference Device** **Atteris Antimicrobial Skin & Wound Cleanser**
Mechanism Of Action	The mechanical action of fluid across the wound removes wound debris, including microorganisms. The change in the indications for use to include removal of microorganisms as a type of wound debris does not change the intended use of the device and does not raise new safety and effectiveness concerns. Substantial equivalence has been confirmed through performance testing of the fluid pressure.	The mechanical action of fluid across the wound removes wound debris.	The mechanical action of fluid across the wound removes wound debris.	The mechanical action of fluid across the wound removes wound debris.
Solution	1 bottle of Surgiphor Solution 0.5% povidone iodine plus vitamin E TPGS in 0.9% saline, pH 4.6 – 7.0 1 bottle of sterile saline, USP, pH 4.0 – 7.0	0.05% chlorhexidine gluconate in 99.95% sterile water for irrigation, USP	1 bottle of Surgiphor Solution 0.5% povidone iodine plus vitamin E TPGS in 0.9% saline, USP, pH 4.6 – 6.4 1 bottle of sterile saline, USP, pH 4.0 – 6.5	Purified water, poloxamer 407, sodium chloride, ethylhexylglycerin, hypromellose, octane-1,2-diol, polyaminopropyl biguanide [PHMB]
Solution Antimicrobial Preservative	0.5% Povidone Iodine	0.05% Chlorhexidine Gluconate	0.5% Povidone Iodine	Polyaminopropyl Biguanide [PHMB]
How Supplied	1 – 450 mL bottle of Surgiphor Solution 0.5% povidone iodine plus vitamin E TPGS in 0.9% saline, USP; 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.	Provided for single use. A 450 mL bottle of Irrisept is double wrapped in CSR and sealed within an outer Tyvek® pouch. The bottle exterior, CSR wraps, and applicator are sterilized by EO gas. The bottle contains aseptically processed Irrisept solution.	1 – 450 mL bottle of Surgiphor Solution 0.5% povidone iodine plus vitamin E TPGS in 0.9% saline, USP; 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.	Provided Non-Sterile In 8 Fluid Ounce Bottle with Sprayer.

Comparison of Technological Characteristics				
Comparison Feature	**Proposed Device** **BD Surgiphor™ Antimicrobial Irrigation System**	**Primary Predicate Device** **Irrisept® Antimicrobial Wound Lavage**	**Secondary Predicate Device** **Surgiphor™ Wound Irrigation System**	**Reference Device** **Atteris Antimicrobial Skin & Wound Cleanser**
Applicator	Polycarbonate cap with a spike threads onto a polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.	Multiport applicator that threads onto the Irrisept bottle.	Polycarbonate cap with a spike threads onto a polypropylene bottle. The user squeezes the bottle to dispense the solution onto the wound.	Sprayer Attachment
Sterilization	The BD Surgiphor™ Antimicrobial Irrigation System is provided terminally sterile to a SAL of 10^{-6} by gamma irradiation. The system is validated in accordance with *ANSI/AAMI/ISO TIR13004: Sterilization of health care products- Radiation - Substantiation of a selected sterilization dose: Method VDmax*^{SD}	Bottle exterior, CSR wraps, and outer packaging conforms to ISO 11135-7 for EO sterilization and ISO 10993-7 for EO residuals whereas the solution is aseptically processed.	The Surgiphor Sterile Wound Irrigation System is provided terminally sterile to a SAL of 10^{-6} by gamma irradiation. The system is validated in accordance with *ANSI/AAMI/ISO TIR13004: Sterilization of health care products- Radiation - Substantiation of a selected sterilization dose: Method VDmax*^{SD}	Provided non-sterile
Biocompatibility	Biocompatible per *ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, Annex A (informative) Biological evaluation tests* as a surface device (breached or compromised) with limited contact (≤ 24 hours). Added Teflon coating to the mold to manufacture the cap. The components of the mold that are Teflon coated do not come into contact with the fluid-contacting portions of the cap.	Biocompatible per ISO 10993 testing for a surface device with breached or compromised surface contact and a limited duration (≤ 24 hours)	Biocompatible per *ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, Annex A (informative) Biological evaluation tests* as a surface device (breached or compromised) with limited contact (≤ 24 hours). No Teflon Coating on the mold to manufacture the cap.	Biocompatible per ISO 10993 testing
Preservative Effectiveness over Shelf-Life	Demonstrated per USP <51> testing.	Demonstrated per USP <51> testing.	Demonstrated per USP <51> testing.	Demonstrated per USP <51> testing.
Storage Temperature	Store at room temperature. Avoid freezing and excessive heat above 40°C (104°F)	10°C to 30°C	10°C to 30°C	Unknown

Performance Testing

There are no technological differences between the two versions of the Surgiphor System. The change to the BD labeled indication for use to include removal of "microorganisms" as a type of wound debris does not change the intended use of the device and does not raise new safety and effectiveness concerns. Substantial equivalence has been confirmed through performance testing as summarized below.

The following tests were submitted under K202071 and remain valid for the subject device:

- Preservative Antimicrobial Effectiveness
  - USP <51> Antimicrobial Effectiveness Testing
- Endotoxins and Pyrogens
  - USP <85> Bacterial Endotoxins Test
  - USP <151> Pyrogen Test (USP Rabbit Test)
  - USP <161> Medical Devices- Bacterial Endotoxin and Pyrogen Tests
- Biocompatibility
  - ISO 10993-1 Biological Evaluation of Medical Devices
- Fluid Pressure Testing
- Nonclinical Wound Healing Study

The following tests were conducted to support the transfer of the Surgiphor System to BD:

- Sterilization
  - ANSI/AAMI/ISO TIR13004:2013, Sterilization of Health Care Products - Radiation - Substantiation of a Selected Sterilization Dose: Method VDmax^{SD}
  - ANSI/AAMI/ISO 11137:2006/ (R) 2015 & A1:2013 & A2:2019, Sterilization of Health Care Products — Radiation – Part1: Requirements for development, validation and routine control of a sterilization process for medical devices
  - ANSI/AAMI/ISO 11137-1:2018/: Sterilization of Health Care Products — Microbiological methods – Part 1: Determination of the population of microorganisms on product
  - ANSI/AAMI/ISO 11137-2:2019/: Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
  - ANSI/AAMI/ISO 11137-2:2013/ (R) 2019, Sterilization of Health Care Products — Radiation – Part 2: Establishing the sterilization dose.
  - (AAMI) ST72:2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing
- Packaging and Shelf-Life
  - ISO 11607 - 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

- Stability Testing
  - ICH Q1A(R2) - Stability Testing of New Drug Substances and Products
  - USP <51> Antimicrobial Effectiveness Testing
  - Free Iodine Determination
  - % Available Iodine Determination
  - Osmolality Determination
  - USP <791> pH Determination
- Biocompatibility
  - ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Substantial Equivalence Conclusion

The performance testing conducted demonstrates that the subject BD Surgiphor™ Antimicrobial Irrigation System is substantially equivalent to the primary predicate, Irrisept device and the secondary predicate, Surgiphor Wound Irrigation System in intended use and technological characteristics and this premarket notification supports the addition of "microorganisms" as a type of wound debris removed by the device in the labeled indications for use.