October 23, 2020

Orthophor, LLC
℅ Elizabeth O'Keeffe
Director of Regulatory Affairs
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K202071
Trade/Device Name: SURGIPHOR Wound Irrigation System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH
Dated: July 24, 2020
Received: July 27, 2020

Dear Elizabeth O'Keeffe:

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,

For Kimberly Ferlin, PhD
Acting 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: 06/30/2020
See *PRA Statement on last page.*

510(k) Number *(if known)*

K202071

Device Name

SURGIPHOR™ Wound Irrigation System

Indications for Use *(Describe)*

The SURGIPHOR™ Wound Irrigation System is a wound cleansing delivery system intended to loosen and remove wound debris.

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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Philadelphia, PA 19107

510(k) Summary for K202071

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the SURGIPHOR™ Wound Irrigation System is provided below.

Date	July 24, 2020
Submitted by	Orthophor, LLC 125 S. 9th Street Sheridan Building, Suite 1001 Philadelphia, PA 19107 Phone: (215) 801-1590
510(k) Contact	Secure BioMed Evaluations Elizabeth O'Keeffe 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com
Trade Name	SURGIPHOR™ Wound Irrigation System
Common Name	Jet Lavage
Code –Classification	FQH: Class II, 21 CFR 880.5475
Predicate Device	K080779, Irrisept™ Wound Debridement and Cleansing System
Secondary Predicate Device	K181428, Clyra Wound Irrigation Solution

Device Description

SURGIPHOR™ Wound 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™ (0.5% Povidone Iodine) solution 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 from wounds. The SURGIPHOR™ Wound Irrigation System is provided as a two part terminally sterilized system with 475 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.

Intended Use/Indications for Use

The SURGIPHOR™ Wound Irrigation System is a wound cleansing delivery system intended to loosen and remove wound debris.

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Technological Characteristics

The subject device has the same intended use as the predicate device and substantially equivalent technological characteristics as the predicate device and/or the secondary predicate device in terms of principles of operation, material performance, and biocompatibility.

Predicate Comparison Justification

The SURGIPHOR™ Wound Irrigation System is substantially equivalent to an FDA 510(k) Cleared predicate device and shares technological features with one FDA 510(k) Cleared secondary predicate device. The following sections summarize the testing that was performed to demonstrate substantial equivalence to the predicate device.

Non-clinical Testing – Bench Study Comparison

The subject device has mechanical properties substantially equivalent to commercially available devices with the same intended uses. The following characteristics were evaluated:

Performance Testing

Device Component	pH	Osmolality	Chemical Analysis	Particulates
SURGIPHOR™	X	NA	X	X
SurgiRinse™	X	X	NA	X

The subject device was also tested to show equivalent mechanical action to the predicate device, demonstrating that the pressure produced during the use of the device is sufficient to agitate, loosen and remove debris from wounds.

Further testing to demonstrate the device preservative povidone iodine is effective throughout the intended use duration of the device (24 hours after opening) was conducted following USP<51>.

Performance Testing – Animal Study

The SURGIPHOR™ Wound Irrigation System was evaluated in a full thickness porcine wound healing model demonstrating that the test article does not appear to inhibit normal wound healing when compared to the predicate device.

Non-Clinical Testing – Biocompatibility

The SURGIPHOR™ Wound Irrigation System is categorized as a surface device with limited contact with breached or compromised surfaces per ISO 10993-1 2007, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and FDA’s Guidance for Industry and Food and Drug Administration Staff “Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” (June 16, 2016). The device was evaluated for the appropriate biocompatibility characteristics,

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as well as conducting a Toxicological Risk Assessment to evaluate the safety of the device and each of the device components.

Clinical Testing

The SURGIPHOR™ Wound Irrigation System was evaluated in a Human Repeat Insult Patch Test with a primary endpoint assessing the irritation potential in humans. Additionally, a Human Abraded Skin Patch Test for Pyrogenicity was conducted with a primary endpoint of assessing the potential for pyrogenic response in humans.

Substantial Equivalence Discussion

The SURGIPHOR™ Wound Irrigation system is substantially equivalent in function and intended use to the predicate device. A comparison of the subject device to the predicate device and secondary predicate device is shown in the following table.

Trait	SURGIPHOR™ Wound Irrigation System	IRRISEPT Wound Debridement and Cleansing System (Predicate Device)	Clyra Wound Irrigation Solution (Secondary Predicate Device)	Comparison/ Equivalent to
510(k) number	K202071	K080779	K181428	N/A
FDA Regulation	880.5475	880.5475	Unclassified	Same as predicate
Product Code	FQH	FQH	FRO	Same as predicate
Product Classification	Class II	Class II	Unclassified	Same as predicate
Use	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Equivalent to predicate device
Intended Use	The SURGIPHOR™ Wound Irrigation system is a wound cleansing delivery system intended to loosen and remove wound debris	The IRRISEPT™ Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris	Clyra Wound Irrigation Solution is intended for use by healthcare professionals for cleansing, irrigating, moistening and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as 1st and 2nd degree burns, stage I - IV pressure ulcers, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post surgical wounds, grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings	Equivalent to predicate
Mechanism of Action	Agitate and mechanically loosen and remove wound debris	Agitate and mechanically loosen and remove wound debris	Agitate and mechanically loosen and remove wound debris	Equivalent to predicate devices

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Trait	SURGIPHOR™ Wound Irrigation System	IRRISEPT Wound Debridement and Cleansing System (Predicate Device)	Clyra Wound Irrigation Solution (Secondary Predicate Device)	Comparison/ Equivalent to
Composition	0.5% Povidone Iodine 0.9% Saline Phosphate Buffered Saline TPGS Vitamin E Potassium Iodide	0.05% Chlorhexidine Gluconate 0.9% Saline	Copper Sulphate Potassium Iodide Sodium Chloride Water	Equivalent to predicate (does not raise different questions of safety or effectiveness), similar to secondary predicate device

Substantial Equivalence Conclusions

The intended use is identical and the Indications for Use statement for the SURGIPHOR™ Wound Irrigation System is substantively the same as that of the predicate device. The differences in ingredients do not raise different questions of safety or effectiveness. The performance testing and Toxicological Risk Assessment demonstrate that the SURGIPHOR™ Wound Irrigation System is at least as safe and effective as the predicate. Therefore, the information in this premarket notification demonstrates that the SURGIPHOR™ Wound Irrigation System is substantially equivalent to the predicate device.