May 16, 2023

Smith & Nephew Medical Limited
Zoe Smith
Regulatory Affairs Specialist
101 Hessle Road
Hull, HU3 2BN
United Kingdom

Re: K220964
Trade/Device Name: VERSAJET Hydrosurgery System (III)
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: Class II
Product Code: FQH
Dated: March 2, 2023
Received: March 2, 2023

Dear Zoe Smith:

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,

David Krause -S

for Julie A. 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.

510(k) Number *(if known)*
K220964

Device Name
VERSAJET III Hydrosurgery System

Indications for Use *(Describe)*
The VERSAJET III Hydrosurgery System cuts, ablates and removes tissue and foreign matter from wounds via pressurized saline. The system is intended for applications that in the physician's judgment, require sharp debridement:
- wound debridement (acute and chronic wounds, burns),
- soft tissue debridement and cleansing of surgical sites.

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 (K220964)

21 CFR 807.92 (a)(1): Submitter's Information	
510(k) Owner Name	Smith & Nephew Medical Ltd
Address	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Establishment Registration Number	8043484
Contact Name	Zoe Smith
Telephone Number	+447583672659
Date Prepared	15th May 2023
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	VERSAJET III Hydrosurgery System
Common Name	Hydrosurgery System
Review Panel	General and Plastic Surgery
Regulation Number	21 CFR 880.5475
Regulatory Class	Class II
Product Code	FQH
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**510(k) Number:** K143115 **Device Name:** VERSAJET II Hydrosurgery System

21 CFR 807.92 (a)(4): Device Description

The VERSAJET III Hydrosurgery System consists of a reusable console, foot pedal and single-use, sterile hand pieces.

The VERSAJET III Hydrosurgery System can be used to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. This is a debridement system intended for wound and soft tissue debridement, and cleansing of the surgical site. This is achieved via the delivery of a pressurized stream of sterile saline fluid. The fluid acts to tangentially ablate the surface of the tissue and propel excised tissue and debris out of the wound. The debris and fluid are directed into the handpiece into a flexible tube, which carries the effluent to the drain or collection canister.

The pressure can be adjusted using either the foot switch or on the touchscreen front panel of the console. Pressure settings range from 1-10 in factory pre-set increments, with the pressure increasing with each higher setting number, depending on the needs of a particular application.

21 CFR 807.92 (a)(5): Intended Use / Indications for Use

The VERSAJET III Hydrosurgery System cuts, ablates and removes tissue and foreign matter from wounds via pressurized saline. The system is intended for applications that in the physician's judgment, require sharp debridement:
- wound debridement (acute and chronic wounds, burns),
- soft tissue debridement and cleansing of surgical sites.

21 CFR 807.92 (a)(6): Comparison of Technological Characteristics between the Subject and Predicate Devices
The technological principle for debridement and cleansing of the surgical site for the VERSAJET III Hydrosurgery System is identical to the predicate device, the VERSAJET II Hydrosurgery System. Both the subject and predicate devices use a pressurized stream of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The subject and predicate devices are based on the following same technological elements: - Consists of two primary components: an electrically (mains) powered console that is reusable equipment, and single-use, sterile disposable handpieces with tubing and pump cartridge. - Uses a pressurized stream of sterile fluid to cut, ablate and remove tissue - The pressure settings can be adjusted from 1-10 at factory pre-set increments. The indications for use are similar for the subject and predicate device, although the phrase "pulse lavage irrigation" is removed and the mechanism of action is clarified by the addition of "The VERSAJET III Hydrosurgery System cuts, ablates and removes tissue and foreign matter from wounds via pressurized saline". There are no technological differences between the subject and predicate devices that raise new questions of safety or efficacy. Only minor modifications have been made to the device to improve reliability and enhance quality.
21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
The following tests were completed to prove safety and effectiveness of the subject device, as well as demonstrate substantial equivalence in performance to the predicate device: - Pressure, Flow Rate and Hand Piece Reliability - Hand Piece Aerosolization & Bacterial Transmission - Console Cut-Off Pressure - Console Reliability - Operating Environment - Human Factors Summative Testing Guidance and Standards Used - Electrical safety per IEC 60601-1 - EMC per IEC 60601-1-2 - Human factors per IEC 62366, IEC 60601-1-6 and applicable guidelines listed in FDA Guidance Document: Applying Human Factors and Usability Engineering to Medical Devices (FDA 2011-D0469) - Bench top performance testing including challenge conditions

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
No clinical data were provided to support the demonstration of substantial equivalence.
21 CFR 807.92 (b)(3): Conclusions drawn
In establishing substantial equivalence to the predicate device, Smith & Nephew Medical Ltd evaluated the indications for use, principle of operation, materials, technology, product specifications and energy requirements of the device. Performance testing, software verification testing, electromagnetic compatibility testing and electrical safety testing has been completed to demonstrate that the VERSAJET III Hydrosurgery System is substantially equivalent to the predicate device for the intended use.