March 30, 2023

Rochal Technologies LLC
William Coulston
Director, Quality & Regulatory Affairs
1200 Network Boulevard
San Antonio, Texas 78249

Re: K223377
Trade/Device Name: BIASURGE Advanced Surgical Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 27, 2023
Received: February 28, 2023

Dear William Coulston:

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 A. Morabito -S

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.

510(k) Number *(if known)*
K223377

Device Name
BIASURGE Advanced Surgical Solution

Indications for Use *(Describe)*
Biasurge Advanced Surgical Solution is indicated for use in mechanical cleansing and removal of debris, 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.

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

1. Submitter's Name and Address
Rochal Technologies LLC.
12000 Network Blvd, Ste B200
San Antonio, Texas, 78249

2. Submitter's Contact Person
William J. Coulston
Director of Quality & Regulatory Affairs
(210) 375-9349 ext 110
wcoulston@rochaltech.com

3. Date of 510(k) Summary Preparation:
29 March 2023

4. Device Name (Proprietary)
Biasurge Advanced Surgical Solution

5. Common Name
Wound Cleanser, Irrigation Solution, Wound Lavage

6. Classification Name
Dressing, Wound, Drug

7. Device Class
Unclassified

8. Device Code
FRO

9. Reference Devices
K192349, Bactisure
K222804, Irrisept
K203835, MIS Solution

10. Description of Device
BIASURGE Advanced Surgical Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. BIASURGE Solution is provided in a soft polypropylene 1000mL container with a spikeable port. BIASURGE Solution is composed of Purified Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Hypromellose, Octane-1,2-diol, Polyaminopropyl Biguanide [PHMB; a preservative], EDTA Disodium, EDTA Trisodium.

11. Intended Use of Device

Biasurge Advanced Surgical Solution is indicated for use in mechanical cleansing and removal of debris, including microorganisms, from wounds.

12. Legally Marketed Device for substantial equivalence comparison:

Feature Being Compared	PROPOSED DEVICE BIASURGE	PREDICATE DEVICE K160192 (BIAKŌS)	Discussion of characteristics
Design	DESCRIPTION BIASURGE Advanced Surgical Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. BIASURGE Solution is provided in a soft polypropylene 1000mL container with a spikeable port. BIASURGE Solution is composed of Purified Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Hypromellose, Octane-1,2-diol, Polyaminopropyl Biguanide [PHMB; a preservative], EDTA Disodium, EDTA Trisodium.	Description of Device Atteris Antimicrobial Skin & Wound Cleanser helps in the mechanical removal of debris and foreign material from the skin, wound or application site. Atteris Antimicrobial Skin & Wound Cleanser is a pure, colorless, isotonic cleanser that is safe. The cleanser has a six month expiration due to the preservative that provides bactericidal and fungicidal properties through the action of the antimicrobial (PHMB). A preservative, PHMB, at a concentration of 0.1% w/w is added to the product to inhibit the growth of microorganisms such as, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, Escherichia coli, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA),	The proposed device's design is similar to the predicate device and reference devices K192349, Bactisure and K203835, MIS Solution. The preservative is PHMB in both the subject and predicate devices. The mechanism of action for both devices is mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as microorganisms, dirt and debris. The mechanical action of the irrigation can be provided by either a manual syringe or powered irrigation device. The design is substantially equivalent.

		and fungus *Candida albicans* within the product.	
Indications for Use	INDICATIONS Biasurge Advanced Surgical Solution is indicated for use in mechanical cleansing and removal of debris, including microorganisms, from wounds. Rx Only	Intended Use of Device Atteris Antimicrobial Skin & Wound Cleanser is intended for over-the-counter (OTC) and professional use as follows: a. For Over-the-Counter Use:…. b. Professional Use: (Rx Only) 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. Rx Only and OTC	The description and indications for use are the same as the reference device, K203835, MIS Solution. The subject device is a single-patient-multiple use product. The Indications for Use are substantially equivalent.
Materials	1 L polypropylene bag with a single twist-off port	HDPE bottle with Trigger Sprayer	Different. However, both are plastics commonly used in legally marketed medical device irrigation solutions or wound cleansers. These minor differences do not raise new questions of safety or effectiveness. The materials are substantially equivalent.
Other Features	Sterile – Moist Steam	Non-sterile	Provided sterile, but single-patient multi-use for a period of 28-days. Predicate: non-sterile, single patient multi-use for a period of 28-days.

			Other features are substantially equivalent.
Biocompatibility Testing	ISO 10993-1 Requirements	ISO 10993-1 Requirements	Biocompatibility is substantially equivalent
Chemical Safety	Same as the predicate device	Purified Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Hypromellose, Octane-1,2-diol, Polyaminopropyl Biguanide [PHMB; a preservative], EDTA Disodium, EDTA Trisodium	Same. Chemcial safety is substantially equivalent.
Packaging	1 L polypropylene bag with a single twist-off port Overwrap	HDPE Trigger Sprayer	Different but allows for the same use, i.e., both allow for mechanical removal of debris from wounds. Reference devices K192349, Bactisure and K203835, MIS Solution were leveraged to support the equivalence of the packaging. The reference device MIS Solution shares the same/similar packaging. The packaging is substantially equivalent.

13. Performance Testing

Biasurge Advanced Surgical Solution has been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe and as effective as its predicate device. USP <51> testing demonstrates the chosen preservative is appropriate for the product formulation. The results of the aging study indicate the product is stable and effective for the proposed shelf life. Reference devices K192349, Bactisure and K203835, MIS Solution were leveraged to support the equivalence of the packaging.

14. Substantial Equivalence Conclusion

As discussed in the 510(k) submission, Biasurge Advanced Surgical Solution has similar indications for use, product form and function, as the predicate device, Atteris Antimicrobial Skin & Wound Cleanser (K160192). The safety evaluation meets the requirements as detailed by ISO 10993.

On the basis of the information presented in this 510(k) submission, Rochal Technologies LLC, concludes (a) Biasurge Advanced Surgical Solution is substantially equivalent to the predicate device, as it has the similar intended uses, the same technology, packaging, and sterilization as the predicate and reference devices; and (b) demonstrates the device is at least as safe and effective as the legally marketed predicate device.