May 25, 2023

Armis Biopharma, Inc.
Angela Mallery
Principle Product Development Specialist
2950 E. Harmony Road Ste. 252
Fort Collins, Colorado 80528

Re: K220759
Trade/Device Name: Armis VeriCyn Wound Wash
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH, FRO
Dated: April 18, 2023
Received: April 18, 2023

Dear Angela Mallery:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.05.25 13:09:44 -04'00'

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)*
K220759

Device Name
VeriCyn® Wound Wash

Indications for Use *(Describe)*
The Armis VeriCyn® Wound Wash is to be used with a lavage system to create mechanical movement at the wound surface by delivery of a solution and is indicated for use in cleansing and removal of foreign material including micro-organisms and debris from wounds (such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first degree and partial thickness burns, grafted and donor 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.

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510(k) SUMMARY
K220759

Date Prepared	May 25, 2023
Applicant	Armis Biopharma 2950 E. Harmony Road Ste. 252 Fort Collins, CO, 80528
Contact Person	Franklin Okumu, Ph.D. Vice President of Product Development 908-635-4172
Device Trade Name	VeriCyn® Wound Wash
Device Classification	Class 2 21 CFR 880.5475 FQH / FRO / General Hospital Lavage, Jet VeriCyn® Wound Wash
Predicate Device	K161165 Next Science™ Irrigation Solution
Reference Device	K151186 Stay Fresh Hydrocolloid Dressing K160192 Atteris Antimicrobial Skin & Wound Cleanser Rochal Industries
Indications for Use	The Armis VeriCyn® Wound Wash is to be used with a lavage system to create mechanical movement at the wound surface by delivery of a solution and is indicated for use in cleansing and removal of foreign material including micro-organisms and debris from wounds (such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first degree and partial thickness burns, grafted and donor sites).
Device Description	The ARMIS VeriCyn® Wound Wash is an aqueous solution for irrigation and debridement of wounds. The solution is a clear, colorless, no-odor aqueous solution that is used to remove debris, including microorganisms from wounds though the use of a lavage system. ARMIS VeriCyn® Wound Wash contains: Hydrogen Peroxide, Acetic Acid, Disodium EDTA and Purified water. VeriCyn® Wound Wash has been tested for compliance with ISO 10993.

Comparison of Technological Characteristics	Minor differences exist between VeriCyn® and Next Science™ Irrigation Solution, these differences do not raise different questions of safety and effectiveness when compared to the predicate device. Therefore, VeriCyn® is considered substantially equivalent to Next Science™ Irrigation Solution. • The difference in materials and composition do not raise any new questions of safety and effectiveness. The materials of construction of VeriCyn® are non-novel to wound wash products cleared by FDA. Each ingredient has a stated purpose, literature data to support its function, and testing demonstrated there are no new questions raised related to safety or effectiveness compared to the predicate. The difference in composition do not raise any new questions of safety and effectiveness. The composition of the materials of the lavage solution are similar between the subject device and the predicate device. VeriCyn® uses a two-preservative system designed to provide preservative effectiveness for the shelf life of the product. • The difference in pH do not raise any new questions of safety and effectiveness. During intended use of the product the pH of VeriCyn® increase to a higher, physiological, pH upon contact with the skin or wound; this is based on the low concentration of acetic acid. The predicate contains a higher concentration of acetic acid and sodium acetate as a pH buffer system that is used to control changes in pH and would maintain lower pH upon contact with skin or wounds than the non-buffered VeriCyn® product. Therefore, no additional risks have been identified related to pH. The difference in sterility does not raise any new questions of safety and effectiveness VeriCyn® has been tested against USP<51>, equivalent to a non-sterile reference device.

Equivalence Comparison				
	Subject Device VeriCyn® Wound Wash (K220759)	**Predicate Device Next Science™ Irrigation Solution (K161165)**	**Reference Device Stay Fresh Hydrocolloid Dressing (K151186)**	**Reference Device Atteris Antimicrobial Skin & Wound Cleanser Rochal Industries (K160192)**
Rx / OTC	Rx	Rx	Rx and OTC	Rx and OTC
Product Code	FQH / FRO	FQH / FRO	FRO	FRO
Intended Use	Wound lavage	Wound lavage	Wound dressing	Wound Dressing
Indications for Use	Prescription (Rx) use: The Armis VeriCyn® Wound Wash is to be used with a lavage system to create mechanical movement at the wound surface by delivery of a solution and is indicated for use in cleansing and removal of foreign material including micro-organisms and debris from wounds (such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first degree and second degree partial thickness burns, grafted and donor sites).	To be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.	For Over-the-Counter Use: The Stay Fresh Hydrocolloid dressing acts as a barrier to bacterial penetration and is indicated for first aid to cover minor cuts, minor abrasions, and minor lacerations Rx Use: Under the supervision of a healthcare professional, the Stay Fresh Hydrocolloid dressing is intended for use as a primary dressing for exuding wounds that acts as a barrier to bacterial penetration, for use on first and second degree burns, surgical wounds, pressure ulcers, dermal ulcers, as well as minor cuts, abrasions, lacerations.	For Over-the-Counter 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. 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.
Composition	Purified Water Acetic Acid Hydrogen Peroxide Disodium EDTA	Purified water Ethanol Acetic acid Sodium acetate Benzalkonium chloride	Hydrogen Peroxide Inert polymer matrix Superabsorbent particles Polyurethane film	Purified Water Poloxamer 407 Sodium Chloride EDTA Hypromellose Sensivas Polyaminopropyl Biguanide
Color	Clear	Clear	N/A	Clear
Clarity	No visible particles	No visible particles	N/A	No visible particles
pH	3.0-3.8	unknown	N/A	unknown
Mechanism of Action	Mechanical removal of debris	Mechanical removal of debris	Wound dressing	Mechanical removal of debris
Packaging	Single use package	Single use package	Pouch	Single use package
Biocompatibility	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Biocompatible per ISO 10993
How supplied	Non-sterile	Sterile	Sterile	Non-sterile
Single patient Use	Single patient Use	Single patient Use	Single patient Use	Single patient Use

Non-Clinical Tests Performed	Non-Clinical testing was conducted, and results were substantially equivalent the prior non-clinical testing including visual and chemical tests, biocompatibility, and a wound-wash study. **Testing** Clarity, Color, pH, and Viscosity were tested. — Device met internal specifications Preservative Effectiveness USP <51> (pass) Bioburden USP <61> and <62> (pass) Cytotoxicity per ISO 10993-5 (pass) Sensitization per ISO 10993-10 (pass) Irritation ISO 10993-10 (pass) Acute Systemic Toxicity per ISO 10993-11 (pass) Material Mediated Pyrogenicity ISO 10993-11 (pass)
Conclusion	Conclusion(s) drawn from the nonclinical tests demonstrate the device is as safe, as effective, and performs as well as the identified legally marketed predicate device (K161165 Next Science™ Irrigation Solution).