January 8, 2026

Kane Biotech Inc
Valerie Acosta
Regulatory Affairs Specialist
190 - 100 Innovation Drive
Winnipeg, MB R3T 6G2
Canada

Re: K252759
Trade/Device Name: revyve® Antimicrobial Skin and Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 8, 2025
Received: December 8, 2025

Dear Valerie Acosta:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MUSTAFA A. MAZHER
-S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252759

Device Name
revyve® Antimicrobial Skin and Wound Cleanser

Indications for Use *(Describe)*
Rx use: revyve® Antimicrobial Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for mechanical cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I - IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and superficial second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions.

OTC use: revyve® Antimicrobial Skin and Wound Cleanser for OTC use is intended for mechanical cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations, and minor burns.

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.

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I SUBMITTER

Kane Biotech Inc.
190-100 Innovation Drive Winnipeg, Manitoba Canada
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Phone: (204) 453-1301Contact Person: Valerie Acosta
Email: regulatory@kanebiotech.com

Prepared: January 5th, 2026

II DEVICE

Name of Device: revyve® Antimicrobial Skin and Wound Cleanser
Common Name: Liquid Wound Wash
Classification Name: Unclassified
Regulatory Class: Unclassified
Product Code: FRO

III PREDICATE DEVICES

Primary Predicate: Atteris™ (BIAKOS) Antimicrobial Skin & Wound Cleanser (K160192)

Secondary Predicate: NAWAlution Skin and Wound Cleanser (K141660)

IV DEVICE DESCRIPTION

revyve® Antimicrobial Skin and Wound Cleanser is a clear, colorless liquid containing poloxamer 407, EDTA, sodium citrate/citric acid, polyhexanide (PHMB) and glycerol. PHMB at a concentration of 0.1% w/w is added as preservative to prevent microbial growth, within the product during shelf-storage. This skin and wound cleanser will be packaged in 4 fluid oz (118.3 mL) polyethylene squeeze bottle. revyve® Antimicrobial Skin and Wound and Cleanser will be used for mechanically cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, first and superficial second-degree burns, post- surgical wounds and abrasions. The mechanical action of moving across the wound provides for the mechanism of action and aids in the removal of foreign material such as dirt, debris, and microorganisms. It will be provided in non-sterile form, labeled for single patient, single use only.

The device will be available as both a Rx and OTC product.

V INDICATIONS FOR USE

Rx use: revyve® Antimicrobial Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for mechanical cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and superficial second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions.

OTC use: revyve® Antimicrobial Skin and Wound Cleanser for OTC use is intended for mechanical cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations, and minor burns.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Summary of the technological characteristics compared to the predicate device [21 CFR 807.92(a)(6)]				
	Candidate Device	**Predicate Devices**		**SE Discussion**
Characteristics	revyve® Antimicrobial Skin and Wound Cleanser (K252759)	Primary Predicate: Atteris™ (BIAKOS) Antimicrobial Skin & Wound Cleanser (K160192)	Secondary Predicate: NAWAlution Skin and Wound Cleanser (K141660)	
Classification	Unclassified	Unclassified	Unclassified	Same
Intended Use				
Rx	revyve® Antimicrobial Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for mechanical cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and superficial second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions.	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.	NAWAlution for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first- and second-degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.	Nearly identical clinical indications in both primary and secondary predicated; both for mechanical cleansing of wounds. Does not raise questions related to safety and/or efficacy.

	OTC	revyve® Antimicrobial Skin and Wound Cleanser for OTC use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations, and minor burns.	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.	NAWAlution for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.	Nearly identical clinical indications; both for mechanical cleansing of wounds. Does not raise questions related to safety and/or efficacy.
Technology		Aqueous	Aqueous	Aqueous	Same. Does not raise questions related to safety and/or efficacy.
Preservative Effectiveness		USP <51>	USP <51	USP <51	Same
Biocompatibility Assessment		Biocompatible	Biocompatible	Biocompatible	Same

revyve® Antimicrobial Skin and Wound Cleanser, the proposed device, is substantially equivalent to the proposed predicate device, the Atteris™ (BIAKOS) Antimicrobial Skin and Wound Cleanser. Both are intended for the mechanical cleansing of wounds moistening or lubricating absorbent wound dressings. Additionally, the technological properties of revyve® Skin and Wound cleanser are similar to the primary predicate. The secondary predicate NAWAlution shares the broader inclusion of Stage I-IV pressure ulcers and the same primary intended use of mechanical cleansing, moistening, and debridement of wounds under healthcare professional supervision with minor labeling differences that do not alter the core intended use. Furthermore, revyve® Antimicrobial Skin and Wound Cleanser, Atteris™ (BIAKOS) Antimicrobial Skin & Wound Cleanser, and NAWAlution Skin and Wound Cleanser have the same preservative. Based on the performance testing presented, those differences do not raise new questions of safety and effectiveness.

VII PERFORMANCE DATA

Non-Clinical Testing

No new biocompatibility testing has been performed for this submission. Test results from testing previously performed on manufacturer's own device are applicable to this device. Results from testing on manufacturer's previously cleared revyve® Antimicrobial Wound Gel (K241809) are applicable to this device, which contains identical ingredients and formulation components. The completed testing includes the following:

- ISO 10993-5: ISO MEM Elution Using L-929 Mouse Fibroblast
- ISO 10993-11: ISO Materials Mediated Rabbit Pyrogen Test
- ISO 10993-10: ISO Guinea Pig Maximization Sensitization
- ISO 10993-11: ISO Acute Systemic Toxicity
- ISO 10993-10: ISO Intracutaneous Irritation

Performance Testing

USP preservative effectiveness testing demonstrates the chosen preservative is performing as intended and appropriate for product formulation. Verification testing of the subject device was conducted to confirm that the modifications did not adversely affect device performance. Testing includes the following:

- pH
- Appearance
- TAMC/TYMC
- PHMB
- Disodium EDTA
- Preservative Effectiveness

Preservative effectiveness testing was performed in accordance with USP <51> to evaluate the in-product microbial control capability of the preservative system during shelf storage. The following challenge organisms were utilized as part of the performance testing to assess preservative efficacy:

- *Aspergillus brasiliensis*
- *Candida albicans*
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus aureus (MRSA)*

The Certificate of Analysis for the subject device demonstrated that the device met all predetermined acceptance criteria and performed as expected. No new clinical or bench performance testing was required, as all other performance characteristics are supported by data from the manufacturer's own cleared device (K241809), to which the subject device is substantially equivalent.

Animal Testing

No animal testing was conducted for the subject device. All biocompatibility and performance characteristics are supported by data from the manufacturer's previously cleared revyve® Antimicrobial Wound Gel (K241809) which contains identical ingredients and formulation components.

VIII CONCLUSIONS

Based on the verification information presented and provided in this submission, Kane Biotech Inc, concludes that revyve® Antimicrobial Skin and Wound Cleanser is substantially equivalent to the predicate devices with respect to intended use, technological characteristics, and performance. The modifications described in this submission do not raise new questions of safety or effectiveness.