May 24, 2023

Kane Biotech, Inc.
% Albert Rego
Consultant
Albert Rego, PhD, Inc
24501 Cabot Road, Suite 122
Laguna Hills, California 92653

Re: K223259
Trade/Device Name: coactiv+™ Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 18, 2022
Received: October 24, 2022

Dear Albert Rego:

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)*
K223259

Device Name
coactiv+™ Antimicrobial Wound Gel

Indications for Use *(Describe)*
Rx: The coactiv+™ Antimicrobial Wound Gel is indicated for management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial & full thickness wounds, large surface area wounds and surgical incisions for adult populations.

OTC: The coactiv+™ Antimicrobial Wound Gel is indicated for management of minor cuts, minor lacerations, minor burns (1st degree burns) and abrasions for adult populations.

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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(5) 510(k) Summary

I SUBMITTER

Kane Biotech Inc.
290-100 Innovation Drive
Winnipeg, Manitoba
Canada
R3T 6G2

Phone: 204-453-1301

Contact Person: Lori Christofalos

II DEVICE

Name of Device: coactiv+™ Antimicrobial Wound Gel
Common Name: Dressing, Wound, Drug
Classification Name: Unclassified
Regulatory Class: Unclassified
Product Code: FRO

III PREDICATE DEVICE

Prontosan Wound Gel X (K130857)
Rochal Antimicrobial Wound Gel (K192527)

IV DEVICE DESCRIPTION

The coactiv+™ Antimicrobial Wound Gel is a white, odorless hydrogel that provides a moist wound environment conducive to wound healing. The coactiv+™ Antimicrobial Wound Gel provides preservative properties through an antimicrobial (PHMB) to help inhibit microbial colonization within the gel during shelf storage. Chronic wounds are known to contain non-viable tissue. The coactiv+™ Antimicrobial Wound Gel can facilitate debridement through a moist wound environment.

The coactiv+™ Antimicrobial Wound Gel contains water, Poloxamer 407, Glycerol, Trisodium citrate, PHMB (0.1% w/w), Citric acid, Disodium EDTA.

The coactiv+™ Antimicrobial Wound Gel dressing will be supplied in 0.7 oz. (21 g) white/opaque polypropylene (19 x 100 mm) screw cap tubes.

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

V INDICATIONS FOR USE

Rx: The coactiv+™ Antimicrobial Wound Gel is indicated for management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial & full thickness wounds, large surface area wounds and surgical incisions for adult populations.

OTC: The coactiv+™ Antimicrobial Wound Gel is indicated for management of minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns) and abrasions for adult populations.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Summary of the technological characteristics compared to the predicate device [21 CFR 807.92(a)(6)]			
Characteristics	Subject Device coactiv+™ Antimicrobial Wound Gel	Primary Predicate Prontosan Wound Gel X (K130857)	Secondary Predicate Rochal Antimicrobial Wound Gel (K192527
Classification	Unclassified	Unclassified	Unclassified
Indicated wounds (Rx)	ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial & full thickness wounds, large surface area wounds and surgical incisions	ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial & full thickness wounds, large surface area wounds and surgical incisions	ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial & full thickness wounds, large surface area wounds, and surgical incisions
Indicated wounds (OTC)	minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns) and abrasions	minor cuts, minor lacerations, minor burns (1st degree burns) and abrasions	minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns), minor irritations
Technology	Hydrogel dressing	Same	Same
Preservative	0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]),	Same	Same
Performance	USP <51> Preservative effectiveness testing	USP <51> Preservative effectiveness testing	USP <51> Preservative effectiveness testing

Biocompatibility Assessment	Biocompatibility according to ISO 10993-1 surface device with prolonged contact on breached or compromised surfaces.	Biocompatibility testing: ISO 10993-1 surface device with prolonged contact (>24 hours to <30 days) on breached or compromised surfaces.	Biocompatibility according to ISO 10993-1

Prontosan Wound Gel X, the proposed primary predicate device, and ROCHAL Antimicrobial Wound Gel, the secondary predicate device, have identical indications for use. Each device is designed as hydrogels with the intended use of creating a moist wound environment conducive to healing. Additionally, the indications for use, and technological properties of the coactiv+™ Antimicrobial Wound Gel are similar to those of the reference devices. ROCHAL Antimicrobial Wound Gel, and coactiv+™ Antimicrobial Wound Gel contain same gelling agent as major ingredient and known safety profile. Furthermore, coactiv+™ Antimicrobial Wound Gel, ROCHAL Antimicrobial Wound Gel and Prontosan Wound Gel X contain the same preservative.

Buffering system used for maintenance of pH of the coactiv+™ Antimicrobial Wound Gel is different from both predicate devices. However, based on the results of the performance testing summarized below, this difference does not raise new questions of safety and effectiveness.

VII PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

The biocompatibility evaluation for coactiv+™ Antimicrobial Wound Gel was conducted in accordance with the FDA Blue Book Memorandum #G95-I "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity ISO 10993-5: 2009
- Sensitization ISO 10993-10:2010
- Intracutaneous reactivity ISO 10993-10:2010
- Implantation ISO 10993-6:2016
- Acute Systemic toxicity ISO 10993-11:2017
- Pyrogenicity ISO 10993-11:2017
- Genotoxicity ISO10993-3:2014

Performance Testing

USP <51> preservative effectiveness testing demonstrates the chosen preservative is performing as intended and appropriate for product formulation. The results of real-time and accelerated aging study indicate the product is stable and maintains performance for the proposed shelf-life of 2 years. Testing includes the following:

- pH <USP 71>
- Viscosity <USP 912>
- Appearance <USP 3>
- TAMC/TYMC <USP 61>
- Preservative Effectiveness <USP 51>

Animal Testing

The effect of the coactiv+™ Antimicrobial Wound Gel on full thickness wound healing was evaluated using a porcine model to demonstrate that it does not negatively impact normal wound healing.

VIII CONCLUSIONS

The coactiv+™ Antimicrobial Wound Gel has similar indication for use, and technological characteristics to the predicate devices Prontosan Wound Gel X and ROCHAL Antimicrobial Wound Gel and the minor differences in technology do not raise any new questions of safety and effectiveness and the performance data, including biocompatibility, shelf-life testing and bench testing demonstrate substantial equivalence to the predicates.

Based on the information presented in these 510(k) submissions, Kane Biotech Inc, concludes that the coactiv+™ Antimicrobial Wound Gel is substantially equivalent to predicate devices as it has the same intended uses, and demonstrates that it is as safe and effective as legally marketed predicate devices.