



July 19, 2024

Kane Biotech, Inc.
% Valerie Acosta
Principal Consultant - Regulatory Affairs
Acostar Limited
69 Cherryblossom Pvt
Ottawa, K2H0C4
Canada

Re: K241809
Trade/Device Name: coactiv+™ Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 21, 2024
Received: June 21, 2024

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.

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

Indications for Use

510(k) Number (if known)

K241809

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

coactiv+™ Antimicrobial Wound Gel (K223259)

IV DEVICE DESCRIPTION

The coactiv+™ Antimicrobial Wound Gel is a white, odorless gel 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 Subject Device: coactiv+™ Antimicrobial Wound Gel (K223259)
Classification	Unclassified	Same
Indicated wounds (Rx)	ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1 st and 2 nd degree burns, partial & full thickness wounds, large surface area wounds and surgical incisions	Same
Indicated wounds (OTC)	minor skin scrapes, minor cuts, minor lacerations, minor burns (1 st degree burns) and abrasions	Same
Technology	Hydrogel dressing	Same
Preservative	0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]),	Same
Performance	USP <51> Preservative effectiveness testing	Same
Biocompatibility Assessment	Biocompatibility according to ISO 10993-1 surface device with prolonged contact on breached or compromised surfaces.	Same

coactiv+™ Antimicrobial Wound Gel (K223259), the proposed predicate device, is the same as the subject device as described by Special 510(K) program – a change to the submitter’s own legally marketed device. All technological and performance data remain the same.

VII SUMMARY OF MODIFICATION

The labeling has been revised to eliminate the previous restriction on usage to 21g/week (90 g/month). This was supported by a Toxicological Risk Assessment providing assurance of the safety of the coactiv+.

VIII PERFORMANCE DATA

The following performance data continue to support and 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.

IX CONCLUSIONS

Based on the information presented, Kane Biotech Inc, concludes that the updated label for coactiv+™ Antimicrobial Wound Gel is substantially equivalent to previously cleared 510(k) predicate devices as it has the same indication for use, technological characteristics, intended uses, and demonstrates that it is as safe and effective as legally marketed predicate devices.