



September 22, 2026

ACTO GmbH
Ahmet Kilic
General Manager
Büchnerstrasse 11 - 38118 Braunschweig
Schulstrasse 8 - 31613 Wietzen-Holte
Braunschweig, 38118
Germany

Re: K254168
Trade/Device Name: Actolind® (06.3637. Actolind® Gel Plus)
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 21, 2026
Received: August 21, 2026

Dear Ahmet Kilic:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,


YU-CHIEH CHIU -S

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

Indications for Use

510(k) Number (if known)

K254168

Device Name

Actolind® Gel Plus

Indications for Use (Describe)

OTC Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of minor cuts, minor abrasions, minor lacerations, and minor burns.

Professional Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and superficial partial thickness (2nd degree) burns, partial and full thickness wounds, large surface area wounds and surgical incisions.

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

1. Submitter's Name and Address

ACTO GmbH

Büchnerstrasse 11, 38118 Braunschweig Germany

2. Submitter's Contact Person

Irem Esin

Regulatory Affairs Responsible

register@actogmbh.com

3. Date of 510(k) Summary Preparation

September 19, 2026

4. Device Name (Proprietary)

Actolind® Gel Plus

5. Predicate Device

Prontosan Wound Gel

B. Braun Medical, Inc.

Regulatory Class: Unclassified, Product Code: FRO

510(k) K163430, May 23, 2017

6. Common Name

Wound Cleanser, Wound Dressing, Wound Care Gel

7. Device Classification

Unclassified

8. Device Code

FRO

9. Comparison of Features

Feature being Compared	Proposed Device <i>Actolind® Gel Plus</i>	Predicate Device <i>Prontosan® Wound Gel</i>	Comparison
510(k) No	K254168	K163430	-
Product Classification	Unclassified	Unclassified	Same
Intended Use of the Device	OTC Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of minor cuts, minor abrasions, minor lacerations, and minor burns. Professional Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and superficial	OTC Use: Prontosan® Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasions, lacerations, and minor burns. Professional Use: Prontosan® Wound Gel is intended to cleanse and moisten the wound bed and for the management of ulcers, 1st and 2nd degree burns, partial and	Same

	partial-thickness (2 nd degree) burns, partial and full thickness wounds, large surface area wounds and surgical incisions.	full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.	
Type of Use	Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)	Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)	Same
Appearance	Clear, colorless, and odorless wound care hydrogel	Clear, colorless, virtually odorless hydrogel ¹	Same
Mechanism of action	The primary mode of action of the device-led product is maintaining a moist wound environment.	The primary mode of action of the device-led product is maintaining a moist wound environment.	Same
Packaging	10,30,50,100,250 mL ABL tubes (Aluminum Barrier Laminate) with screw caps containing pre-inserted aluminum foil liners	30 ml low-density polyethylene squeeze bottles with screw caps ²	Difference 1
Sterility	Non-sterile	Sterile	Difference 2
Characteristics	Hydrogel	Hydrogel	Same
Materials	Purified water, Poloxamer, 0.1% Polyhexamethylenebiguanide HCl [PHMB], Cocamidopropyl PG-Dimonium Chloride Phosphate (ColaLipid C), Monopropylene glycol Hydroxypropyl Guar Ammonium lactate	Purified water, Undecylenamidopropyl betaine, Polyaminopropyl biguanide [PHMB], Glycerol, Hydroxyethylcellulose ³	Difference 3

10. Discussion

Difference 1: Packaging materials are different but the device performance remains the same and does not raise different questions of safety and effectiveness.

Difference 2: Actolind® Gel Plus is a non-sterile medical device. The device contains a preservative agent that inhibits microbial growth within the container for the shelf-life.

Difference 3: Actolind® Gel Plus and the predicate devices are aqueous wound gels containing 0.1% PHMB. The subject device differs from the predicates in the

¹ This information appears on page 1 in the Device Description section of K163430.

² This information appears on page 2 in the Device Description section of K163430.

³ This information appears on page 1 in the Device Description section of K163430.

composition and concentrations of the remaining formulation components. The differences provide in the table above under Article 9.

Actolind® Gel Plus is similar in form, fit, and function to the primary predicate device (Prontosan® Wound Gel), which are legally marketed.

The ingredients more closely match the predicate devices; however, while purified water is the primary component in all devices. All devices are in form of hydrogels with only different gelling agents. The device only differs from the predicate devices in their surfactant substance, with the predicate device's surfactant being undecylenamidopropyl betaine, a polar amphoteric surfactant, and proposed device's surfactant being Poloxamer 188 non-ionic triblock copolymer, a widely and safely used surfactant. The device also contains, an additional surfactant Cocamidopropyl PG-Dimonium Chloride Phosphate (ColaLipid C).

In summary, all three devices are gels containing antimicrobial preservative agents to inhibit microbial growth within the product while the product is on the shelf.

Although the devices have different chemical contents, the devices are biocompatible. The proposed device and the predicate devices have the same intended uses.

Therefore, the difference of chemical formulas between the subject and predicate devices, reference device does not raise new or different questions of safety or effectiveness.

11. Description of Device

Actolind® Gel Plus is a clear, colorless and odorless hydrogel containing Poloxamer 188, Monopropylene glycol, Hydroxypropyl Guar, Ammonium lactate, Polyhexamethylenebiguanide HCl (preservative), Cocamidopropyl PG-Dimonium Chloride Phosphate (ColaLipid C) and purified water as basis formulation. Actolind® Gel Plus is used to moisten the wound bed and clean the wound.

An antimicrobial preservative agent, PHMB, is incorporated into the product, at a concentration of 0.1% w/w. Based on in vitro effectiveness testing, PHMB acts as a preservative to reduce the growth of microorganisms in the non-sterile wound gel during shelf storage.

Indication For Use

OTC Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of minor cuts, minor abrasions, minor lacerations, and minor burns.

Professional Use: Actolind® Gel Plus is intended to cleanse and moisten the wound bed and for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and superficial partial-thickness (2nd degree) burns, partial and full thickness wounds, large surface area wounds and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

12. Performance Testing

Actolind® Gel Plus has been subjected to ISO 10993 biocompatibility studies (Cytotoxicity, Acute systemic toxicity, Material-mediated pyrogenicity, Sensitization and Irritation) to demonstrate that the device is as safe and as effective as its predicate devices. This product is only for limited use (< 24 h) based on biocompatibility testing.

The preservative effectiveness has been supported by USP <51> testing. Additionally, test results have demonstrated preservative effectiveness against the following thirteen microorganisms:

Staphylococcus aureus ATCC 6538
Pseudomonas aeruginosa ATCC 9027
Escherichia coli ATCC 8739
Candida albicans ATCC 10231
Aspergillus brasiliensis ATCC 16404
Acinetobacter baumannii ATCC 19606
Enterobacter cloacae ATCC 13047
Enterococcus faecalis ATCC 51299
Enterococcus faecium ATCC 700221
Proteus mirabilis ATCC 25933
Serratia marcescens ATCC 8100
Methicillin -Resistant Staphylococcus aureus (MRSA) ATCC BAA-1717
Staphylococcus epidermidis ATCC 49134

*For to support the role of PHMB, as a preservative, to inhibit microbial growth USP <51> preservative testing demonstrated using with an expanded list of organisms.

The results of real-time aging stability study indicate the product is expected to be stable and effective for a shelf life of at least 36 months in its unopened packaging.

13. Substantial Equivalence

As discussed in this 510(k) Submission, Actolind® Gel Plus is substantially equivalent in function and has the same intended use as the predicate device Prontosan® Wound Gel. The device and the predicate devices are both intended for the cleansing and moistening of wounds and both share the same antimicrobial preservative agent and only differ on the type of the surfactants they use. The safety evaluation of the proposed device meets the requirements as detailed by eCFR 21 Volume 8 Chapter 1 and ISO.

On the basis of the information presented in this 510(k) submission, ACTO GmbH concludes that Actolind® Gel Plus is substantially equivalent to the predicate device.