February 7, 2020

Rochal Industries, LLC
William Coulston
Quality & Regulatory Manager
12000 Network Blvd, Ste B200
San Antonio, Texas 78249

Re: K192527
Trade/Device Name: Rochal Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 3, 2020
Received: January 6, 2020

Dear William Coulston:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K192527

Device Name
Rochal Antimicrobial Wound Gel

Indications for Use *(Describe)*

ROCHAL Antimicrobial Wound Gel is intended for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), first- and second-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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K192527

Device Name
Rochal Antimicrobial Wound Gel

Indications for Use *(Describe)*
ROCHAL Antimicrobial Wound Gel is intended for the management of minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns), minor irritations.

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.**

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# 510(k) Summary

1. **Submitter's Name and Address**
Rochal Industries LLC.
12000 Network Blvd, Ste B200
San Antonio, Texas, 78249

2. **Submitter's Contact Person**
William J. Coulston
Quality & Regulatory Manager
(210) 375-9349 ext 125
wcoulston@rochalindustries.com

3. **Date of 510(k) Summary Preparation:**
7 February 2020

4. **Device Name (Proprietary)**
Rochal Antimicrobial Wound Gel

5. **Common Name**
Wound Dressing

6. **Classification Name**
Dressing, Wound, Drug

7. **Device Class**
Unclassified

8. **Device Code**
FRO

9. **Description of Device**

ROCHAL Antimicrobial Wound Gel provides a moist environment to wound surfaces. ROCHAL Antimicrobial Wound Gel is a safe and gentle colorless gel. The gel provides preservative properties through the antimicrobial (PHMB). ROCHAL Antimicrobial Wound Gel:

- Resists microbial colonization within the dressing during shelf storage.
- Provides an amorphous gel covering

Facilitates autolytic debridement through a moist wound environment. Wounds experience some level of autolytic debridement where the body's own enzymes breakdown necrotic tissue.

ROCHAL Antimicrobial Wound Gel contains:
Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Octane-1-2-diol, Polyaminopropyl Biguanide (preservative: PHMB 0.1% w/w) Edetate disodium (EDTA), Edetate trisodium (EDTA)

**10. Intended Use of Device**

Rochal Antimicrobial Wound Gel is intended for over-the-counter (OTC) and professional (Rx) use as follows:

- For Over-the-Counter Use: ROCHAL Antimicrobial Wound Gel is intended for the management of minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns), minor irritations.

- Professional Use: ROCHAL Antimicrobial Wound Gel is intended for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), first- and second-degree burns, partial- and full-thickness wounds, large surface area wounds, and surgical incisions.

These indications are similar to the predicate device.

**11. Legally Marketed Device for substantial equivalence comparison:**

| **Feature Being Compared** | **SUBJECT DEVICE** Rochal Antimicrobial Wound Gel | **PREDICATE DEVICE** Prontosan Wound Gel X (K130857) | **DISCUSSION** |
|---|---|---|---|
| **Indications for Use (Rx)** | Rochal Antimicrobial Wound Gel is intended for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), first and second-degree burns, partial and full thickness wounds, large surface area wounds, and surgical incisions. | K130857: Rx: Prontosan® Wound Gel X is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial and full thickness wounds, large surface area wounds and surgical incisions. | The same. |
| **Indications for Use (OTC)** | ROCHAL Antimicrobial Wound Gel is intended for the management of minor skin scrapes, minor cuts, minor lacerations, minor burns (1st degree burns), minor irritations. | K130857: OTC: Prontosan Wound Gel X is indicated for the management minor cuts, minor lacerations, minor burns (1st degree burns), and abrasions. | Similar – slight rewording but within the same type and degree of injury |
| **Technology** | Clear, colorless gel | Clear, colorless gel | Similar – different formulation but does not raise different questions related to safety or effectiveness. |
| **Performance** | USP<51> preservative effectiveness testing | USP <51>, modified Strike Through Barrier testing | Similar – both use PHMB as a preservative. |
| **Biocompatibility** | Biocompatibility Testing: ISO 10993-1, surface device with prolonged contact (>24hours to 30 days) on breached or compromised | Biocompatibility Testing | The subject device has demonstrated to be safe for use as a surface device with prolonged contact (>24hours to |

| | | | |
|---|---|---|---|
| | surfaces | | 30 days) on breached or compromised surfaces |

**12. Performance Testing**

Rochal Antimicrobial Wound Gel has been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe and as effective as its predicate device. Additionally, a large-animal, full-thickness wound healing study was conducted to demonstrate safety. USP<51> preservative effectiveness testing demonstrates the chosen preservative is appropriate for a product formulation. The results of real-time aging study indicate the product is stable and maintains performance for the proposed shelf life of six months.

**13. Substantial Equivalence Conclusion**

Rochal Antimicrobial Wound Gel has very similar indications for use, and similar product form and function as the predicate device, Prontosan Wound Gel X (K130857).

On the basis of the information presented in this 510(k) submission, Rochal Industries LLC, concludes (a) that Rochal Antimicrobial Wound Gel is substantially equivalent to the predicate device, as it has the same intended uses as the predicate device; and (b) demonstrates the device is as safe and effective as the legally marketed predicate device.