May 2, 2025

Seriously Clean, Ltd
% Jordan Elder
Director of Regulatory Affairs
Regulatory Compliance Associates
10411 Corporate Drive
Suite 102
Pleasant Prairie, Wisconsin 53158

Re: K243457
Trade/Device Name: Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 29, 2024
Received: November 7, 2024

Dear Jordan Elder:

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,

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

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)*
K243457

Device Name
Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel

Indications for Use *(Describe)*
The Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is intended to be used for Over-The-Counter and Prescription Use. The Over-The-Counter use is intended for the following indications:
• For use on minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns.
• To moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement.

The Prescription Use Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is indicated for the following uses:
• Use with dermal irritation, sores, injuries and ulcers of dermal tissues.
• Moistening and lubricating absorbent wound dressings and the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions.
• Management of partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), trauma wounds, and various dermatoses including atopic dermatitis.

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:

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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."

510(K) SUMMARY

The following information is provided as required by 21 CFR §807.87 for the **Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel** 510(k) Premarket Notification.

Seriously Clean, Ltd. **Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel** **510(k) Summary**		
Submission Sponsor	**Seriously Clean, Ltd.** 1075 W. Kathryn St., Suite 6 Nixa, MO 65714 USA Phone: 417-725-2816 Website: www.nixall.com	
Submission Contact	Kip Glass COO Email: kip@nixall.com 417.725.2116 Seriously Clean, Ltd 1075 W. Kathryn St., Suite 6 Nixa, MO 65714 USA	
Device Names	• **Proprietary Trade Name:**	Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel
	• **Common Name:**	Dressing, Wound, Drug
	• **Regulatory Classification Names:**	Unclassified
Device Class	• **Regulation Number:**	None (Pre-Amendment Device)
	• **Regulatory Classification:**	Unclassified
	• **Product Code:**	FRO

DATE PREPARED: January 12, 2024

PREDICATE DEVICE(S):

Substantial equivalence is claimed to the following devices as related to intended use, design, and material characteristics:

K150799

- Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel;
- Puracyn® Plus Antimicrobial Hydrogel Professional Formula

DEVICE DESCRIPTION

Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel

The Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is a hypochlorous acid hydrogel solution applied topically to skin and wound areas.

The hydrogel dressing is supplied in various packaging configurations. The OTC hydrogel and the prescription use hydrogel contain hypochlorous acid, a known antimicrobial, which serves as a preservative to inhibit the growth of microorganisms in the hydrogel during shelf-life. The OTC and RX products are supplied non-sterile.

INTENDED USE/INDICATIONS FOR USE

The Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is intended to be used for Over-The-Counter and Prescription Use. The Over-The-Counter use is intended for the following indications:

- For use on minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns.
- To moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement.

The Prescription Use Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is indicated for the following uses:

- Use with dermal irritation, sores, injuries and ulcers of dermal tissues.
- Moistening and lubricating absorbent wound dressings and the wound bed and facilitate autolytic debridement of acute and chronic dermal lesions.
- Management of partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), trauma wounds, and various dermatoses including atopic dermatitis.

TECHNOLOGICAL CHARACTERISTICS

The Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is an opaque, hydrogel that is topically applied to skin and wound areas. The gel helps maintain a moist wound environment to assist with wound healing. The Nixall hydrogels contain hypochlorous acid, a known antimicrobial preservative, which is shown to inhibit microorganisms within the container.

A comparison of technological characteristics between the subject and predicate devices are provided in the table below.

	Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel	***Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel; Puracyn®***	***Conclusion***

		***Plus Antimicrobial Hydrogel Professional Formula* (K150799)**	
Product Code	FRO	FRO	**Identical**
Regulation	N/A - Unclassified	N/A - Unclassified	**Identical**
Technology	The Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel is a hypochlorous acid hydrogel solution applied topically to skin and wound areas. The gel helps maintain a moist wound environment.	Aqueous based topical hydrogel maintaining a moist wound environment and encouraging autolytic debridement	**Identical**
Preservatives	Hypochlorous Acid Sodium Hypochlorite	Hypochlorous Acid Sodium Hypochlorite	**Similar**
Preservative Effectiveness	Yes – Conforms to USP <51>	Yes – Conforms to USP <51>	**Identical**
Biocompatible	Yes	Yes	**Identical**
Intended Use / Indications for Use	***OTC*** • For use on minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. • To moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement. ***RX*** • Use with dermal irritation, sores, injuries and ulcers of dermal tissues. • Moistening and lubricating absorbent wound dressings and the wound bed and facilitate autolytic debridement of	***OTC*** Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel is intended for OTC use to relieve itch and pain from minor skin irritations, minor cuts, exit sites, minor lacerations, minor abrasions and minor burns, including sunburns. Hydrogel is also intended to moisten and lubricate absorbent wound dressings and moisten the wound bed. A moist wound and skin environment facilitates autolytic debridement and is beneficial to wound management and the healing process. ***RX*** Puracyn® Plus Antimicrobial Hydrogel Professional Formula is intended for use by healthcare professionals to moisten the wound bed and	**OTC: Essentially Identical** **RX: Essentially Identical**

	acute and chronic dermal lesions. • Management of partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), trauma wounds, and various dermatoses including atopic dermatitis.	facilitate autolytic debridement of acute and chronic dermal lesions, as indicated below. Puracyn® Plus Antimicrobial Hydrogel Professional Formula relieves itch and pain associated with dermal irritation, sores, injuries and ulcers of dermal tissue in addition to moistening and lubricating absorbent wound dressings. Puracyn® Plus Antimicrobial Hydrogel Professional Formula is indicated for the management of partial or full thickness wounds such as 1st and 2nd degree burns, stage I – IV pressure ulcers, diabetic and stasis ulcers, abrasions and skin irritations, surgical wounds (donor and graft sites, incisions), trauma wounds, and various dermatoses including atopic dermatitis.	
Sterility	Not Sterile	Not Sterile	**Identical**

The subject devices are similar in technology to the predicate devices in that the products are topical hydrogels, which encourage autolytic debridement. The products contain viscosity-enhancing agents that impart hydrogel characteristics and hypochlorous acid and sodium hypochlorite as preservatives. There are no significant differences between the subject and predicate devices with respect to the intended use.

NON-CLINICAL TESTING

To demonstrate the safety and effectiveness of the Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel, Seriously Clean completed the following non-clinical testing:

- ISO 10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for in-vitro Cytotoxicity
- ISO 10993-6 – Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation
- ISO 10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-18 – Biological Evaluation of Medical Devices – Part 18: Chemical characterization of medical device materials within a risk management process

- ISO 10993-23 – Biological Evaluation of Medical Devices – Part 23: Tests for Irritation
- USP <51> - Antimicrobial Effectiveness Test
- USP <85> - Bacterial Endotoxins Test

Expanded testing consistent with USP <51> supports the inhibition of growth of microorganisms within the container. The biocompatibility testing conducted according to ISO 10093-1 demonstrates that the hydrogels are biologically safe for human use.

CONCLUSION

Based on the above analysis and performance testing results, the subject devices are considered as safe and effective as the predicate devices. Therefore, it is concluded that the Nixall Antimicrobial Solutions™ Skin & Wound Hydrogels (subject devices) are substantially equivalent to the identified predicate devices.