November 10, 2023

Winner Medical Co., Ltd.
Mingni Liu
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road,
Longhua District
Shenzhen, Guangdong 518109
China

Re: K231564
Trade/Device Name: Skin and Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 10, 2023
Received: October 10, 2023

Dear Mingni Liu:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231564

Device Name
Skin and Wound Cleanser

Indications for Use *(Describe)*

Prescription Use:

Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

OTC Use:

Skin and Wound Cleanser for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, minor abrasions, minor lacerations and minor burns.

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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Tab #6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K231564

1.Date of Submission:May 31, 2023

2.Submitter Identification

Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen City, Guangdong Province, 518109, China

Contact Person: Mingni Liu

Position: Regulatory Affairs Specialist

Tel: +86-755 28138888

Fax: +86-755 28134588

Email: 2346@winnermedical.com

3.Identification of Proposed Device

Trade/Proprietary Name: Skin and Wound Cleanser

Common name: Wound wash Solution

Regulatory Information

Classification Name: Dressing, Wound, Drug;

Classification: Unclassified;

Product Code: FRO;

Review Panel: General & Plastic Surgery;

4.Identification of Predicate Device

Predicate Device:

510(k) Number: K141660

Product Name: NAWAlution Skin and Wound Cleanser

Manufacturer: NAWA Heilmittel GmbH

Reference Device:

510(k) Number: K161623

Product Name: Prontosan Wound Irrigation Solution

Manufacturer: B. Braun Medical Inc

5.Device Description

The proposed devices, Skin and Wound Cleanser, is a clear, colorless solution that is intended for wound management including cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze).The solution of Skin and Wound Cleanser contains purified water, PHMB, undecylenamidopropyl betaine, and trace ingredients (allantoin, citric acid). During the application of product, fluid moving across the wound aids in the removal of foreign objects such as dirt and debris. Skin and Wound Cleanser solution contains PHMB, a known antimicrobial preservative, which is shown to inhibit the growth of microorganisms such as Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus niger, Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococcus faecalis (VRE) to maintain quality of the product during storage of the wound cleansing solution.

6. Intended Use Statement

Prescription Use:

Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

Over-The-Counter:

Skin and Wound Cleanser for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, minor abrasions, minor lacerations and minor burns.

7.Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-6:2016 Biological Evaluation of Medical Devices- Part 6: Tests for Local Effects after implantation.

ISO 10993.10-2010 Biological evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2017 Biological Evaluation Of Medical Devices- Part 11: Tests For Systemic Toxicity.

USP <51> Antimicrobial Effectiveness Testing

Preservative efficiency testing was conducted with the proposed device according to USP <51> category 2. The proposed device was tested against the following microorganism: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus niger, Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococcus faecalis (VRE). The test results demonstrated the effectiveness of Skin and Wound Cleanser to inhibit the growth of microorganisms within the wound cleansing solution.

8.Clinical Test Conclusion

No clinical study is included in this submission.

9.Substantially Equivalent (SE) Comparison

The proposed devices are compared with the following Predicate Devices in terms of intended use, principle of operation, material components, specifications, and performance.

These data came from commercially product labeling and 510(k) summary.

- Predicate Device, K141660，NAWAlution Skin and Wound Cleanser，Manufactured by NAWA Heilmittel GmbH.
- Reference Device, K161623, Prontosan Wound Irrigation Solution, Manufactured by B. Braun Medical Inc.

The following table shows comparison between the proposed device and predicate devices in terms of intended use, performance, material components, principle of operation and etc.

Based on the comparison and analysis, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.

Table 1 Comparison of Intended use, Design and Technological Characteristics

Item	Proposed Device K231564	Predicate Device K141660	Reference Device K161623
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified
Intended Use	**Prescription Use:** Skin and Wound Cleanser for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent	**Prescription Use:** NAWAlution for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent	**Prescription Use:** Prontosan Wound Irrigation Solution is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.

	wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. **Over-The-Counter Use:** Skin and Wound Cleanser for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, minor abrasions, minor lacerations and minor burns.	wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. **Over-The-Counter Use:** NAWAlution for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.	
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Appearance	Clear, colorless solution	Clear, colorless solution	Clear, colorless solution
Application method	Spray bottle; Squeeze bottle	Spray bottle (50 mL (1.8 fluid oz.) – OTC); Spray bottle (8 fluid oz. (237 mL) or 16 fluid oz. (473 mL) – Rx)	Tube applicator; Spray bottle
Characteristics	Aqueous	Aqueous	Aqueous
Density (at 20°C)	0.9 – 1.0 g/ml	0.9 – 1.0 g/ml	0.9 – 1.0 g/ml
Materials	Purified water, PHMB, Undecylenamidopropyl	Purified water, Cocamidopropylbetaine, Zinc Chloride, PHMB,	Purified water, PHMB, Undecylenamidopropyl Betaine

	Betaine, Trace ingredients (allantoin, citric acid)	Hydrochloric acid, Trace Element	
Sterility	Non-sterile	Non-sterile	Sterile

10.Conclusion

Skin and Wound Cleanser is comparable to the predicate device in formulation, manufacturing, packaging and intended use. Winner believes the predicate and subject devices to be substantially equivalent