May 31, 2024

Innovacyn, Inc.
Hungnan Lo
Vice President, Technical Operations
3546 N. Riverside Ave.
Rialto, California 92377

Re: K232080
Trade/Device Name: Puracyn® Plus Antimicrobial Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 26, 2024
Received: April 29, 2024

Dear Hungnan Lo:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232080

Device Name
Puracyn® Plus Antimicrobial Irrigation Solution

Indications for Use *(Describe)*
Puracyn® Plus Antimicrobial Irrigation Solution is applied with irrigation to cleanse and remove debris from wounds.

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

Date Prepared:	4/26/2024
Applicant:	Innovacyn, Inc. 3546 N. Riverside Avenue Rialto, CA 92377
Contact Person:	Hungnan Lo Vice President, Technical Operations 866-787-2296
Device Trade Name:	Puracyn® Plus Antimicrobial Irrigation Solution
Device Code:	FRO
Regulatory Class:	Unclassified

Predicate Device: K133542, Puracyn Plus Skin and Wound Care, Innovacyn, Inc.

Device Description:
Puracyn® Plus Antimicrobial Irrigation Solution is a wound irrigation formula that contains hypochlorous acid as an antimicrobial preservative to inhibit the growth of micro-organisms within the solution.

Puracyn® Plus Antimicrobial Irrigation Solution is supplied sterile in 1000 mL and 3000 mL flexible LLDPE bag configurations. Each bag is packaged in a sealed foil pouch.

Indications For Use:
Puracyn® Plus Antimicrobial Irrigation Solution is applied with irrigation to cleanse and remove debris from wounds.

Comparison of Technological Characteristics:
A comparison of technological characteristics between Puracyn® Plus Antimicrobial Irrigation Solution and the predicate device Puracyn Plus™ Skin and Wound Care (K133542) is provided in the following **Table 1:**

Table 1. Comparison of Puracyn® Antimicrobial Irrigation Solution to Predicate Device

	SUBJECT DEVICE: Puracyn® Plus Antimicrobial Irrigation Solution (K232080)	**PRIMARY PREDICATE: Puracyn Plus™ Skin and Wound Care (K133542)**
Composition	Purified water, Hypochlorous acid, phosphates	Purified water, Hypochlorous acid, phosphates
Description	Clear, colorless solution packaged in flexible plastic bags	Clear, colorless, non-sterile solution packaged in plastic PET bottles
Volume	1000 mL, 3000 mL	1000 ml to 55 ml
Indications	Puracyn® Plus Antimicrobial Irrigation Solution is applied with	

	SUBJECT DEVICE: Puracyn® Plus Antimicrobial Irrigation Solution (K232080)	PRIMARY PREDICATE: Puracyn Plus™ Skin and Wound Care (K133542)
	irrigation to cleanse and remove debris from wounds.	Professional Use: Puracyn Plus™ Skin and Wound Care is intended for use by healthcare professionals for cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as Is' and 2nd degree burns, stage I - IV pressure ulcers, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post-surgical wounds, grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings.
Mechanism(s) of Action	The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects.	The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris.
Antimicrobial Preservative	Preservative: Hypochlorous acid	Preservative: Hypochlorous acid
Microbial Control and Sterility	Meets USP <71> and USP <51>	Meets USP <51>
Biocompatibility	Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements
Use	Multiple use within a single patient	Multiple use for multiple patients

Discussion:
The Puracyn Plus Antimicrobial Irrigation Solution is substantially equivalent to the primary predicate, Puracyn Plus Skin and Wound Care (K133542), with respect to intended use and technological characteristics such as chemical composition, mechanism of action, preservative, and biocompatibility. While there are slight differences in packaging/volume, use, and wording for the indications for use, these do not raise new questions of safety and effectiveness when compared to the primary predicate device.

Performance Testing:
The following studies have been performed to support the safety and effectiveness of the subject device:

- Stability Studies per ICH Q1A(R2)
- Biocompatibility studies in accordance with ISO10993-1
- Packaging Testing in accordance with ISO 11607-1 and ISO 11607-2
- Sterilization in accordance with ISO 11737-1 and 11737-2
- Endotoxin Testing per USP<85>
- Preservative Antimicrobial Effectiveness Testing per USP <51>

- Sterility Testing per USP <71>
- Bioburden Testing per USP <61> and USP<62>

Conclusion:
In summary, the Puracyn Plus Antimicrobial Irrigation Solution is substantially equivalent to the primary predicate in essential aspects critical to its clinical use. The noted differences in packaging/volume, use, and wording for the indications for use align with the subject device's specific application and operational requirements. These differences do not raise new questions of safety and effectiveness, thereby supporting its substantial equivalence to the primary predicate device.