January 5, 2026

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

Re: K251757
Trade/Device Name: Puracyn® Plus Antimicrobial Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 7, 2025
Received: November 7, 2025

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.

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)*
K251757

Device Name

Puracyn® Plus Antimicrobial Irrigation Solution

Indications for Use *(Describe)*

Puracyn® Plus Antimicrobial Irrigation Solution is applied with irrigation for mechanical cleansing and removal of debris from wounds, including microorganisms.

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.

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"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

Date Prepared:	12/30/2025
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
Common Name:	Wound Irrigation Solution
Product Code:	FRO/FQH
Device Classification	Unclassified/ Class II (21 CFR 880.5475)

Predicate Device: K232080, Puracyn® Plus Antimicrobial Irrigation Solution, 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 microorganisms within the solution. The mechanical action of the solution moving across the wound, combined with the hydrodynamic shear provided by mechanical irrigation, aids in the removal of debris and contaminants such as dirt, debris, and microorganisms.

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 for mechanical cleansing and removal of debris from wounds, including microorganisms.

Comparison of Technological Characteristics:
A comparison of technological characteristics between Puracyn® Plus Antimicrobial Irrigation Solution and the predicate device (Puracyn® Plus Antimicrobial Irrigation Solution, K232080) is provided in the following table:

	SUBJECT DEVICE Puracyn® Plus Antimicrobial Irrigation Solution	PREDICATE DEVICE Puracyn® Plus Antimicrobial Irrigation Solution	Comparison
Indications	Puracyn® Plus Antimicrobial Irrigation Solution is applied with irrigation for mechanical cleansing and removal of debris from wounds, including microorganisms.	Puracyn® Plus Antimicrobial Irrigation Solution is applied with irrigation to cleanse and remove debris from wounds.	See discussion below
Composition	Purified water, Hypochlorous acid, Sodium phosphates	Purified water, Hypochlorous acid, Sodium phosphates	Same
Description	Clear, colorless solution packaged in flexible plastic bags	Clear, colorless solution packaged in flexible plastic bags	Same
Volume	1000 mL, 3000 mL	1000 mL, 3000 mL	Same
Mechanism(s) of Action	The mechanical action of the solution moving across the wound, combined with the hydrodynamic shear from mechanical irrigation, aids in the removal of debris and contaminants such as dirt and micro-organisms.	The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects.	See discussion below
Antimicrobial Preservative Effectiveness	Preservative: Hypochlorous acid	Preservative: Hypochlorous acid	Same
Biocompatibility	Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements	Same
Packaging Material	Polyethylene flexible bag in a foil over-pouch	Polyethylene flexible bag in a foil over-pouch	Same
Manufacturing Practice	Manufacturing using aseptic techniques	Manufacturing using aseptic techniques	Same
Use	Multiple use within a single patient	Multiple use within a single patient	Same

The subject device has been tested in conjunction with the InterPulse®, Pulsavac®, and MicroAire® jet lavage systems to demonstrate compatibility for use with jet lavage systems. There are no differences in intended uses, biocompatibility, preservative effectiveness, endotoxin limits, packaging, or sterilization information.

Performance Testing:

The following testing was performed to demonstrate substantial equivalence:

- Design Compatibility Testing

Design compatibility testing was conducted to demonstrate that the subject device is compatible with the jet lavage systems InterPulse®, Pulsavac®, and MicroAire® systems.

In addition, the following data from the Sponsor's own predicate was leveraged in support of this submission:

- Stability studies per ICH Q1A(R2)
- Biocompatibility studies per ISO 10993-1
- Packaging testing per ISO 11607-1 and ISO 11607-2
- Sterilization validation in accordance with ISO 11737-1 and ISO 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:

The subject device does not raise new questions of safety or effectiveness when compared to the predicate. All materials, manufacturing methods, and performance characteristics are the same. The device performance has been demonstrated to be compatible with jet lavage systems - InterPulse®, Pulsavac®, and MicroAire® systems. Therefore, the Puracyn® Plus Antimicrobial Irrigation Solution is substantially equivalent to the predicate device.