



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 19, 2015

Innovacyn Incorporated
% Ms. Roshana Ahmed, MA, RAC
OptumInsight Incorporated
4 Innovative Drive
Dundas, Ontario L9H 7P3
Canada

Re: K150799

Trade/Device Name: Puracyn[®] Plus Duo-Care[™] Antimicrobial Wound & Skin Hydrogel
Puracyn[®] Plus Antimicrobial Hydrogel Professional Formula

Regulatory Class: Unclassified

Product Code: FRO

Dated: October 21, 2015

Received: October 21, 2015

Dear Ms. Ahmed:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150799

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

Indications for Use (Describe)

For Over-the-Counter Use: 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.

For Professional Use: Puracyn® Plus Antimicrobial Hydrogel Professional Formula is intended for use by healthcare professionals to moisten the wound bed and 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.

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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"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."

3. 510(k) Summary

Manufacturer Name:	Innovacyn, Inc.
Address:	3546 N. Riverside Avenue Rialto, CA 92377
Contact Name:	Victor Torcat
Title:	Vice President, Regulatory and Compliance
Phone Number:	866-318-3116
Fax Number:	909-428-1947
Date Prepared:	October 15, 2015

Device Proprietary Names:	Puracyn [®] Plus Duo-Care [™] Antimicrobial Wound & Skin Hydrogel; Puracyn [®] Plus Antimicrobial Hydrogel Professional Formula
Common or Usual Name:	Hydrogel Wound Dressing
Classification Name:	Dressing, Wound, Drug
Classification Code:	FRO
Regulation Number:	N/A
Device Classification	Unclassified

Predicate Devices:

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

- Microcyn[™] Skin and Wound Hydrogel, Oculus Innovative Sciences, Inc., K093585
- Anasept[™] Antimicrobial Skin and Wound Gel, Anacapa Technologies, Inc., K073547
- Puricore Wound Hydrogel Spray Dressing, Puricore Inc., K141863
- Epicyn[™] HydroGel, Oculus Innovative Sciences, Inc., K102945

Innovacyn's Puracyn Plus Skin and Wound Care Solutions (K133542) is used as a reference device.

Description of the Device

Puracyn[®] Plus Duo-Care[™] Antimicrobial Wound & Skin Hydrogel and the Puracyn[®] Plus Antimicrobial Hydrogel Professional Formula are opaque and pH balanced hydrogel dressings that are topically applied to skin and wound areas. The gel provides relief from

itching and pain, and helps maintain a moist wound environment to assist with the wound healing process. The hydrogel dressings will be supplied in various packaging configurations. Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel and the Puracyn® Plus Antimicrobial Hydrogel Professional Formula contain hypochlorous acid, a known antimicrobial, which serves as a preservative to inhibit the growth of microorganisms in the hydrogel.

Intended Use/Indications for Use

For Over-the-Counter Use: 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.

For Professional Use: Puracyn® Plus Antimicrobial Hydrogel Professional Formula is intended for use by healthcare professionals to moisten the wound bed and 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.

Technological Characteristics

Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel and the Puracyn® Plus Antimicrobial Hydrogel Professional Formula are opaque and pH balanced hydrogel dressings that are topically applied to skin and wound areas. The gel provides relief from itching and pain, and helps maintain a moist wound environment to assist with the wound healing process. Puracyn® Plus hydrogels contain hypochlorous acid, a known antimicrobial preservative, which is shown to inhibit the growth of microorganisms such as *Candida albicans*, *Aspergillus brasiliensis*, *acinetobacter albumin*, Vancomycin-resistant *Enterococcus* (VRE), *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, and Methicillin-resistant *Staphylococcus aureus* (MRSA) in the hydrogel.

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

	Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel; Puracyn® Plus Antimicrobial Hydrogel Professional Formula	Microcyn™ Skin and Wound HydroGel (K093585)	Anasept™ Antimicrobial Skin and Wound Gel (K073547)	Puricore Wound Hydrogel (K141863)	Epicyn™ HydroGel (K102945)
Technology	Aqueous based topical hydrogel maintaining a moist wound environment and encouraging autolytic debridement	Topical Hydrogel encouraging autolytic debridement	Topical Hydrogel	Aqueous based topical hydrogel maintaining a moist wound environment and encouraging autolytic debridement	Aqueous based topical hydrogel maintaining a moist wound environment and encouraging autolytic debridement
Preservatives	Hypochlorous acid Sodium hypochlorite	Hypochlorous acid Sodium hypochlorite	Sodium hypochlorite	Hypochlorous acid Sodium hypochlorite	Hypochlorous acid Sodium hypochlorite
Antimicrobial Effectiveness	Yes	Yes	Yes	Yes	Yes
Viscosity Increasing Ingredient	Magnesium lithium sodium silicate (nanoclay)	Magnesium lithium fluorosilicate (nanoclay)	Sodium magnesium silicate (nanoclay)	Sodium magnesium fluorosilicate (nanoclay)	Magnesium lithium sodium silicate (nanoclay)
Biocompatible	Yes	Yes	Yes	Yes	Yes

There are no differences between the subject and predicate devices with respect to intended use.

The subject devices are similar in technology to the predicate devices in that the products are topical hydrogels which encourage autolytic debridement and protect the wound against contamination. The products contain viscosity enhancing agents which impart hydrogel characteristics, as well as hypochlorous acid and/or sodium hypochlorite as preservatives. Expanded testing consistent with USP <51> supports that the Free Available Chlorine (FAC) inhibits microbial contamination within the product. As supported by biocompatibility testing according to ISO10093-1, hydrogels are biologically safe.

Non-Clinical Testing

The following studies have been performed to support the safety and effectiveness of the product:

- Stability Studies
- Biocompatibility studies in accordance with ISO10993-1
- Antimicrobial/Preservative Effectiveness Testing per modified USP <51>

Conclusion

Based on the analysis presented above and the results of performance testing, the subject devices are as safe and effective as the predicate devices. Therefore, it is concluded that the subject devices are substantially equivalent to the identified predicate devices.

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