September 20, 2019

Clyra Medical Technologies Inc.
% Tanya Rhodes
President
Rhodes & Associates, Inc
211 Poinciana Lane
Largo, Florida 33770

Re: K181428
Trade/Device Name: Clyra Wound Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 15, 2019
Received: September 17, 2019

Dear Tanya Rhodes:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Cynthia Chang
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181428

Device Name
Clyra™ Wound Irrigation Solution

Indications for Use *(Describe)*
Rx: Clyra Wound Irrigation Solution 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 1st 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.

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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Section 6

510(k) Summary

Clyra™ Wound Irrigation Solution

K181428

1. **Submission Sponsor**

   Clyra Medical Technologies Inc.

   14921 Chestnut St.

   Westminster

   California 92683

   United States

   Contact: Steven V. Harrison

   Title: President

2. **Submission Correspondent**

   Rhodes & Associates, Inc.

   211 Poinciana Lane

   Largo

   FL 33770

   Office Phone: 727-458-4291

   Contact: Tanya Rhodes

   Title: President

3. **Date Prepared**

   9.20.2019

4. **Device Identification**

   Trade/Proprietary Name: Clyra™ Wound Irrigation Solution

   Common/Usual Name: Wound Cleanser

   Classification Name: Dressing, Wound, Drug

Regulation Number:	Unclassified
Product Code:	FRO
Device Class:	Unclassified (Pre-Amendment)
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

K133452 - Puracyn Plus Skin and Wound Care - Innovacyn, Inc. Rialto, CA 92377

6. Indication for Use Statement

Clyra Wound Irrigation Solution 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 1st 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.

7. Device Description

Clyra Wound Irrigation Solution is a clear hypotonic solution topically applied to skin and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). 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. Clyra Wound Irrigation Solution will be supplied in food grade 4 oz. plastic PET bottles with spray inserts and caps. Clyra Wound Irrigation Solution contains Potassium Iodide and Copper Sulphate, which release iodine when combined, resulting in a concentration within the product of 250 parts per million (ppm). The iodine acts as a preservative to inhibit contamination within the solution.

8. Substantial Equivalence Discussion

The following table compares the Clyra Wound Irrigation Solution to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 6A – Comparison of Characteristics

Manufacturer	**Clyra Medical Technologies Inc.**	**Innovacyn Inc.**	**Device Comparison**
Trade Name	**Clyra Wound Irrigation Solution**	**Puracyn Plus Skin and Wound Care**	
510(k) Number	K181428	K133542	Not applicable
Product Code	FRO	FRO	Same
Regulation Number	Unclassified	Unclassified	Same
Regulation Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Same
Prescription Only Indications for Use	**Rx**: Clyra Wound Irrigation Solution 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 1st 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.	**Rx:** 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 Ist 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.	Same Each device is indicated for topical wound care/ irrigation. The Intended Use Statement utilizes the same indications as previously cleared under predicate devices.

Manufacturer	Clyra Medical Technologies Inc.	Inovacyn Inc	Device Comparison
Trade Name	**Clyra Wound Irrigation Solution**	**Puracyn Plus Skin and Wound Care**	
Device Description	Clyra Wound Irrigation Solution is a clear hypotonic solution topically applied to skin and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). 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. Clyra Wound Irrigation Solution will be supplied in food grade 4 oz. plastic PET bottles with spray inserts and caps. Clyra Wound Irrigation Solution contains Potassium Iodide and Copper Sulphate, which release iodine when combined, resulting in a concentration within the product of 250 parts per million (ppm). The iodine acts as a preservative to inhibit contamination within the solution.	Puracyn Plus Skin and Wound Care is a clear hypotonic solution topically applied to skin and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). 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. Puracyn Plus Skin and Wound Care will be supplied in food grade 4 oz. plastic PET bottles with spray inserts and caps.	Same. Additional information regarding Clyra Wound Irrigation Solution preservative system

Manufacturer	Clyra Medical Technologies Inc.	Innovacyn Inc	Device Comparison
Trade Name	**Clyra Wound Irrigation Solution**	**Puracyn Plus Skin and Wound Care**	
Form	The device is supplied in food grade 4 oz plastic PET bottles with spray inserts and caps. This product is preserved and provided non sterile	The device is supplied in food grade 4 oz plastic PET bottles with spray inserts and caps. This product is preserved and provided non sterile.	Same
Ingredients	Copper Sulphate; Potassium Iodide; Sodium Chloride; Water	Hypochlorous Acid; Sodium Hypochlorite; Phosphate; Sodium Chloride; Water	No significant difference. Materials used in each product are similar in their properties to provide a preserved wound irrigation solution
Pre-Clinical Testing	Pre-Clinical Testing included pH, Shelf Life, Chemical Stability, Antimicrobial Preservative Effectiveness,	Pre-Clinical Testing included pH, Shelf Life, Chemical Stability, Antimicrobial Preservative Effectiveness	No significant difference.
Complies with ISO 10993-1	Yes	Yes	No significant difference
Complies with Antimicrobial Test USP<51>	Non-sterile Preserved/Conforming to USP <51>	Non-sterile Preserved/Conforming to USP <51>	Same
Sterile	Non-sterile	Non-sterile	Same
Shelf-Life	Two (2) Years	Two (2) years	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Clyra Wound Irrigation Solution and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Clyra Medical Technologies Inc. completed ISO 10993 biocompatibility testing to establish the safety of Clyra Wound Irrigation Solution for its intended use.

- Cytotoxicity Assay (ISO 10993-5:2009):
- Porcine Wound Healing Study
- Sensitization Test (ISO 10993-10:2010):
- Irritation Test (ISO 10993-10:2010):
- Material medicated pyrogenicity
- Chemical characterization and toxicological risk assessment for systemic toxicity
- Antimicrobial Effectiveness Test (AET) (USP<51>): Clyra Wound Irrigation Solution was evaluated for preservative activity in compliance with USP Antimicrobial Effectiveness Test <51> , designed to test efficacy of preservatives. Exposure to Clyra Wound Irrigation Solution caused an inhibition in Pseudomonas *aeruginosa, E. coli,* Staphylococcus *aureus,* Candida *albicans,* and Aspergillus *brasiliensis* .

- Shelf Life Testing – A maximum shelf life of 2 years has been assigned to the Clyra Wound Irrigation Solution, when stored unopened at ambient temperature, in accordance with the manufacturer's recommendations.

10. Clinical Performance Data

N/A

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise new questions regarding its safety and effectiveness as compared to the predicate device(s).

The Clyra Wound Irrigation Solution, as designed and manufactured, is determined to be substantially equivalent to the predicate device.