April 13, 2018

Aquilabs US LLC
Juan Salcedo
Manager
9205 NW 101st St.
Medley, Florida 33178

Re: K180305
Trade/Device Name: Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 30, 2018
Received: February 2, 2018

Dear Juan Salcedo:

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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180305

Device Name
Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC)

Indications for Use *(Describe)*
OTC Indications: Hychloderm Wound and Skin Care (OTC) is intended for over-the-counter use in the management of minor irritations, minor cuts, minor abrasions, minor burns, minor lacerations, and intact skin and lubrication absorbent wound dressings.

Rx-only Indications: Hychloderm Wound and Skin Care (Rx) is intended for use by healthcare professionals for management of minor irritations, minor cuts, minor abrasions, minor lacerations, cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wound such as, stage I-IV pressure ulcers, diabetic foot ulcers, leg ulcers, 1st and 2nd degree burns, post-surgical wounds, 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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21CFR 807.92.

The assigned 510(k) Number is: __K180305__

Sponsor Information (21 CFR 807.92(a)(1))

Product and Company Information

Date of Preparation:	April 9, 2018
Company:	AQUILABS U.S, LLC.
Address:	9205 NW 101st St Medley FL. 33178
Phone Number:	(+1) 305-885-2255/56
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Contact Person:	Juan Salcedo & Justo Calderon,
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Device Name/Classification (21 CFR 807.92(a)(2))

Device Name:	Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC)
Common name:	Wound Cleanser
Classification Name:	Dressing, wound, drug

Device Biocompatibility Contact Class: A (<24 hrs)

Device Code: FRO

Advisory panel: General and Plastic Surgery

Identification of Legally Marketed Device for Substantial Equivalence Comparison (21 CFR 807.92(a)(3))

Primary Predicate Device: **K133542**, Puracyn Plus™, Skin and Wound Care by Innovacyn, Inc.

Secondary Predicate Device: **K123072**, Vashe® Wound Therapy Solution. **K113693**, Nixal ® Wound and Skin Care.
K113820, Neutrophase® Skin and Wound Cleanser.

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are similar in function and have the same intended use as the predicate device, these indications are similar to that of the predicate device **K133542**, Puracyn plus™, skin and wound care by Innovacyn, Inc. cleared by FDA as a wound and skin care product and other cleared devices such as: **K123072**, Vashe® Wound Therapy Solution. **K113693**, Nixal ® Wound and Skin **K113820**, Neutrophase® Skin and Wound Cleanser. The safety evaluation meets the requirements as detailed in standards USP<51> and ISO 10993. Safety has been established through biocompatibility testing. On the basis of the information presented in this application, Aquilabs concludes that Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are substantially equivalent to the primary and secondary predicate devices as it as has the same intended use as the predicate and the information submitted to FDA which does not raise different questions of safety and effectiveness demonstrating that the device is at least as safe and effective as the legally marketed device. Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) have 0.01% HOCl as preservative.

Device Description (21 CFR 807.92(a)(4))

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are a single-patient single-use, clear liquid solution containing 0.01% hypochlorous acid (HOCl) as preservative in water/saline buffer, that aids the mechanical removal of debris and foreign material from the application site. Dirt, debris and foreign material is mechanically removed by the action of the wound cleanser moving across the wound bed or application site with or without the assistance of a suitable wound dressing (i.e. gauze). It can be used in all stages of wound care and it is an ideal foundation for wound bed preparation. In addition to moistening and lubricating adsorbent wound dressings. It is a clear solution with 0.01% of hypochlorous acid that has been demonstrated to act as a preservative that inhibits microbial contamination within the solution.

OTC Indications:

Hychloderm® Wound and Skin Care (OTC) is intended for over the counter use in the management of minor irritations, minor cuts, minor abrasions, minor burns, minor lacerations and intact skin and lubricating absorbent wound dressings.

Rx Indications:

Hychloderm® Wound and Skin Care (Rx) is intended for use by healthcare professionals for management of minor irritations, minor cuts, minor abrasions, minor lacerations, cleansing, irrigating, moistening, and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wound such as, stage I-IV pressure ulcers, diabetic foot ulcers, leg ulcers, 1st and 2nd degree burns, post-surgical wounds, and lubricating absorbent wound dressings.

Device Technological Characteristics (21 CFR 807.92(a)(6))

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC), are clear liquid solutions containing 0.01% of hypochlorous acid (HOCl) that aids the

mechanical removal of debris and foreign material from the application site. Dirt, debris and foreign material is mechanically removed by the action of the wound cleanser moving across the wound bed or application site with or without the assistance of a suitable wound dressing (i.e. gauze). Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) products contain of 0.01% Hypochlorous Acid as preservative in Water/saline buffer.

Performance Testing

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) have been subjected to in *vitro and in vivo* toxicity/biocompatibility studies to demonstrate that the device is safe for the indications for use. Extensive bench, biocompatibility and animal testing have been performed to support the substantial equivalence of Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC). All of the testing showed that the product functions as intended. Hychloderm® has 0.01% hypochlorous acid that acts as a preservative to help with the inhibition of the bacterial/microbial growth within the solution as supported by preservative effectiveness test USP 51 . The Conclusion of different preservatives effectiveness studies made with Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) shows that the solution is an effective preservative system against bacteria and fungi within the solution according to USP<51> criteria following the 28 day incubation period and following the 56 day re-challenge incubation period.

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are similar in function, claims and have the same intended use as the predicate device: **K133542** Puracyn Plus, and other cleared devices such as: **K123072**, Vashe® Wound Therapy Solution. **K113693**, Nixal ® Wound and Skin **K113820**, Neutrophase® Skin and Wound Cleanser.

On the basis of the information presented in this application, AquiLabs concludes that Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are substantially equivalent to the predicate device. The product is biocompatible and

non-toxic for the intended use. As it as has the same intended use as the predicate and the information submitted to FDA which does not raise different questions of safety and effectiveness; Stability testing supports a shelf life of 12 months for Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC). Its characteristics demonstrates that the device is as safe and effective as the legally marketed device.

Substantial Equivalence Discussion/ Conclusion

Hychloderm®

Active Ingredients:	Hypochlorous Acid: 0.01%
Inactive Ingredients:	Saline buffer (NaCl): 0.005%
	Demineralized/purified water: 99.985%

Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are similar in function and has the same intended use as the predicate device, These indications are similar to that of the predicate device **K133542**, Puracyn plus™, skin and wound care by Innovacyn, Inc. approved by FDA as a wound and skin care product and other cleared devices such as: **K123072**, Vashe® Wound Therapy Solution. **K113693**, Nixal ® Wound and Skin **K113820**, Neutrophase® Skin and Wound Cleanser. The safety evaluation meets the requirements as detailed by USP and ISO. Safety has been established through biocompatibility testing, in-vitro cytotoxicity testing and sensitization testing On the basis of the information presented in this application, Aquilabs concludes that Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) are substantially equivalent to the primary and secondary predicate devices as it as has the same intended use as the predicate and the information submitted to FDA which does not raise different questions of safety and effectiveness demonstrating that the device is as safe and effective as the legally marketed device. Hychloderm Wound and Skin Care (Rx) and Hychloderm Wound and Skin Care (OTC) have 0.01% HOCl as preservative.