



Food and Drug Administration
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October 28, 2016

Helsinn Healthcare SA
% Ms. Barbara A. Binzak Blumenfeld
Buchanan Ingersoll & Rooney PC
1700 K Street Northwest, Suite 300
Washington, District of Columbia 20006

Re: K152533
Trade/Device Name: Xonrid[®] Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 26, 2016
Received: September 26, 2016

Dear Ms. Blumenfeld:

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" (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.

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,

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)

Not assigned

K152533

Device Name

Xonrid® Gel

Indications for Use (Describe)

Under the supervision of a healthcare professional, Xonrid® Gel is indicated to manage and relieve the burning and itching experienced with radiation dermatitis. Xonrid® Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Not intended to be used on open 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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Helsinn Healthcare SA**510(K) SUMMARY****I. SUBMITTER**

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Contact Person: Valentina Tombolini Bossi, Manager, Regulatory Affairs, Medical Device Division
Date Prepared: September 3, 2015

II. DEVICE

Name of Device: Xonrid[®] Gel
Product Code: FRO
Classification: Unclassified
Classification Name: Dressing

III. PREDICATE DEVICES

MimyX[®] Cream (K041342), Stiefel Laboratories, Inc. [primary predicate]
Sinclair Wound and Skin Emulsion[™] (K024367), Sinclair Pharmaceuticals, Ltd.

IV. DEVICE DESCRIPTION

Xonrid[®] Gel is a multi-component prescription medical device product. It is a non-sterile topical water-based gel that forms a protective barrier on skin to increase moisture and reduce water loss.

Under the supervision of a healthcare professional, Xonrid[®] Gel is indicated to manage and relieve the burning and itching experienced with radiation dermatitis. Xonrid[®] Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Not intended to be used on open wounds.

Xonrid[®] Gel contains numerous ingredients that are grouped into several common ingredient classes, including emollients; preservatives; skin conditioning agents; viscosity-increasing agents; emulsifying agents; and binders. Each ingredient is a well-recognized component of topical cosmetic products that primarily provide the skin conditioning and emollient features of Xonrid[®] Gel. Xonrid[®] Gel provides a physical, topical barrier to the skin.

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Xonrid[®] Gel is applied three times per day (or as needed). The product is packaged in a 75 mL bottle equipped with an airless dispensing system and a cap. The bottle is manually operated, with each pump administering approximately 240 µl of product. The product is intended to be used for less than 30 days, and has a 36-month shelf life when stored at ambient temperature.

V. INDICATIONS FOR USE

Under the supervision of a healthcare professional, Xonrid[®] Gel is indicated to manage and relieve the burning and itching experienced with radiation dermatitis. Xonrid[®] Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Not intended to be used on open wounds.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Topical medical devices such as Xonrid[®] Gel typically contain ingredients that are different from any other single device. However, these products typically share functional ingredient categories.

MimyX[®] Cream is selected as the primary predicate because its prescription indication is the most similar to Xonrid[®] Gel (*i.e.*, neither one is indicated for first and second degree burns, as is Sinclair Wound and Skin Emulsion[™]). It has several of the same ingredients as Xonrid[®] Gel, and the functional ingredient classes for each product are largely identical.

Sinclair Wound and Skin Emulsion[™] is also selected as a predicate device because it contains sodium hyaluronate, as does Xonrid[®] Gel. Sinclair Wound and Skin Emulsion[™] also shares several ingredients with Xonrid[®] Gel, and the functional ingredient classes for each product are in large part identical.

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination for Xonrid[®] Gel.

Biocompatibility Testing

Biocompatibility testing meets the criteria of the FDA Blue Book Memorandum #G95-1, "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" (May 1, 1995). According to that document, Xonrid[®] Gel is a surface device used on breached or compromised surfaces for prolonged use (24 hours to 30 days). The tests conducted for Xonrid[®] Gel to support a biocompatibility determination included:

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- *Cytotoxicity Test by Direct Contact* (ISO 10993-5:2009) – Xonrid[®] Gel is non-cytotoxic.
- *Skin Irritation Test, Single Application* (ISO 10993-10:2010) – Xonrid[®] Gel is considered a slight irritant.
- *Skin Irritation Test, Repeated Application* (ISO 10993-10:2010) – Xonrid[®] Gel is considered a slight irritant.
- *Delayed Hypersensitivity Test* (ISO 10993-10:2010) – Xonrid[®] Gel is not sensitizing.

Performance Testing – Bench

Three performance testing bench studies were completed for Xonrid[®] Gel, which included the following:

- *Comparative in vitro Lenitive Efficacy Evaluation by Reconstructed Human Epidermis (“RHE”)* – Xonrid[®] Gel is not a skin irritant, and has no lenitive effect.
- *In vitro Barrier Effect Evaluation by RHE Model* – Xonrid[®] Gel shows a mechanical barrier effect.
- *Comparative Evaluation of Barrier Effect and Washability* – Xonrid[®] Gel shows a mechanical barrier effect and is completely removed with water.

Performance Testing – Clinical

One early-stage, proof-of-concept, single-center, randomized, evaluator-blind clinical study was conducted on 21 healthy volunteer subjects (11 female, 10 male). Measurements were made under two conditions: (1) product applied before and after UV exposure (UVA + UVB); and (2) product applied after UV exposure (UVA + UVB). Assessments included: (1) erythema; (2) skin surface hydration; (3) transepidermal water loss; and (4) cutaneous elasticity. All subjects completed the study, and no adverse events were reported.

VII. CONCLUSIONS

Based upon the biocompatibility studies, as well as the bench and clinical performance testing, Xonrid[®] Gel is safe and suitable for the indications for use. The functional ingredient categories are largely identical between Xonrid[®] Gel and both claimed predicates, Mimyx[®] Cream and Sinclair Wound and Skin Emulsion[™]. Xonrid[®] Gel is expected to perform comparably to these predicates under the supervision of a healthcare professional for the management and relief of burning and itching experienced with radiation dermatitis. Xonrid[®] Gel is also expected to perform comparably to these predicates by helping to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Not intended to be used on open wounds.