September 13, 2019

Roosin Medical Co., Ltd
℅ Charles Shen
Director
Manton Business and Technology Services LLC
37 Winding Ridge
Oakland, New Jersey 07436

Re: K181478
Trade/Device Name: Roosin Xeroform Petrolatum Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 11, 2019
Received: August 13, 2019

Dear Charles Shen:

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, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181478

Device Name
Roosin Xeroform Petrolatum Dressing

Indications for Use *(Describe)*
Roosin Xeroform Petrolatum Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate.

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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510(k) Summary:

Submitter & Foreign Manufacturer Identification

Roosin Medical Co., Ltd.
8 Yuandong Road, KouAn Town, Gaogang,
Taizhou, Jiangsu Province, China 225321
Tel: (086) 523-86908085
Submitter's FDA Registration Number：3007124979

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge 07436
Oakland, NJ
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: September 12. 2019

Device Name:

Trade Name:	Roosin Xeroform Petrolatum Dressing
Common Name:	Wound Dressing
Classification Name:	Dressing, wound, Drug
Product Code:	FRO
Regulation Number:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device Information:

(1) K152970: "Dynarex Xeroform Petrolatum Dressing", manufactured by "Dynarex Corporation" located in Orangeburg, New York, USA

Device description:

Roosin Xeroform Petrolatum Dressing is a type of wound dressing and has ingredients of finely woven mesh gauze infused with a blend of petrolatum and 3% Bismuth Tribromophenate. It is a sterile, single use dressing. This is a combination product.

Roosin Xeroform Petrolatum Dressing is used as a primary contact layer in dressing for wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns.

The dressing has a yellow appearance and is available in the form of pad and in four different sizes (2" x 2", 1" x 8", 4" x 4", 5" x 9"), packaged in pouches.

All dressings are sterilized by gamma radiation using conditions validated following ISO 11137-2: 2013.

Indications for Use:

Roosin Xeroform Petrolatum Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate.

Comparison to Predicate Devices

"Roosin Xeroform Petrolatum Dressing" described in this premarket notification is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K152970: "Dynarex Xeroform Petrolatum Dressing", manufactured by "Dynarex Corporation" located in Orangeburg, New York, USA

The following table shows similarities and differences between our device and the predicate device.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Subject Device	Predicate Device (K152970)
Indication for Use	Roosin Xeroform Petrolatum Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate.	Dynarex Xeroform Petrolatum Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate.
Prescription/ OTC	Prescription	Same
Mechanism	Maintains a moist wound environment	Same
Design/ Material	Cotton Gauze, 3% Bismuth Tribromophenate, and Petrolatum	Same
Color	Light Yellow	Same

Single Use	Yes	Yes
Sterile	Sterile to 10^6 SAL	Same

Roosin Xeroform Petrolatum Dressing and its predicate devices are made from same materials, utilize same principles of operation, and have same indications for use.

Performance tests were conducted following in house procedures, and results for Roosin Xeroform Petrolatum Dressing met all relevant requirements, and are comparable to the predicate devices.

Biocompatibility was evaluated per ISO 19993-1: 2009, and it was found that the subject device is as biocompatible as the predicate device.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Roosin Xeroform Petrolatum Dressing is substantial equivalent to its predicate device.