DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2016

Dynarex Corporation
Mr. James Hurlman
Manager Regulatory Affair
10 Glenshaw Street
Orangeburg, New York 10962

Re: K152970
Trade/Device Name: Dynarex Xeroform Petrolatum Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 29, 2016
Received: September 2, 2016

Dear Mr. Hurlman:

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 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

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)*
K152970

Device Name
Dynarex Xeroform Petrolatum Dressing

Indications for Use *(Describe)*

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 and 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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September 23, 2016

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: 510 (k) Notification - Traditional

Dear Sir / Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby given of the intention of Dynarex Corporation to introduce into interstate commerce for commercial distribution a sterile Xeroform Petrolatum Dressing.

The following is being submitted in conformance with 21 CFR Part 807.87:

| | | |
|---|---|---|
| 1. | **Applicant** | Dynarex Corporation<br>10 Glenshaw Street<br>Orangeburg, NY 10962<br>USA |
| 2. | **Initial Importer** | Dynarex Corporation<br>10 Glenshaw Street<br>Orangeburg, NY 10962<br>USA |
| | Registration No. | 2431014 |
| 3. | **Contact Person** | James Hurlman<br>Official Correspondent / Dynarex Corp<br>10 Glenshaw Street<br>Orangeburg, NY 10962<br>PH: 845-365-8200 Ext 6616<br>Fax: 845-680-6717<br>E-mail: j.hurlman@dynarex.com |
| | **Alternate Only** | Mr. Zalman Tenenbaum<br>President / CEO / Dynarex Corp<br>10 Glenshaw Street<br>Orangeburg, NY 10962<br>PH: 845-365-8200 Ext 6425<br>Fax: 845-365-8201<br>E-mail: z.tenenbaum@dynarex.com |

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4. **Device Proprietary Trade Name** — Dynarex Xeroform Petrolatum Dressing

5. **Manufacturer** — Roosin Medical Co. Ltd
No. 8 Yuandong Road,
Kouan Town
Gaogang, Taizhou,
Jiangsu, China 225321

6. **Factory Address** — Same as Manufacturer.

7. **Listing & Registration Information** — Roosin Medical Co. Ltd
Reg. No.: 3007124979

8. **Device Class** — Unclassified, Div. Surg. Devices Plastic and Reconstructive Surgery Devices

9. **Classification No.** — Product Code: FRO

10. **Identification of Equivalent Marketed Device**

Dynarex would like to claim substantial equivalence to the following device already being marketed in interstate commerce:

Description: Classification Name: Unclassified
Common or Usual Name: Xeroform Petrolatum Wound Dressing

| Product Code | 510(k) Number | Trade Name | Manufacturer |
|---|---|---|---|
| FRO | K973507 | Kendall Xeroform Petrolatum Wound Dressing | Kendall Healthcare Products Company |

**Statement of Similarities and / or Differences with Marketed Device.**

Dynarex Xeroform Petrolatum Dressing is substantially equivalent in safety and effectiveness to Kendall Healthcare Products Company Kendall Xeroform Petrolatum Wound Dressing.

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11. **Indications for Use Statement**

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.

12. **510(k) Summary**

This document serves as our "510(k) Summary", our summary of safety and effectiveness information upon which our equivalence determination is based.

13. **Description of Product**

a) **Classification:** FDA's Division of Surgical Devices (DSD) Plastic and Reconstructive Surgery Devices Branch Two - Skin/Wound Dressing/Aesthetic Injectables (PRSB2) devices as Unclassified – Pre-Amendment, General and Plastic Surgery, Classification Code FRO.

b) **Device Description**: The Dynarex Xeroform Petrolatum Dressing is a sterile, single use, non-adherent dressing consisting of non-woven absorbent gauze saturated with Xeroform with 3% Bismuth Tribromophenate in a petrolatum blend. Packaged in paper metalized chevron pouches and available in Sizes: 2" x 2" ( Item #: 3051), 1" x 8" ( Item #: 3052), 4" x 4" ( Item #: 3053), 5" x 9" ( Item #: 3054)

c) **Principal of Operation and Conditions of Use**:

Dynarex Xeroform Petrolatum Dressing gauze is a type of medical dressing and has ingredients finely wovens mesh medical gauze infused with a blend of petrolatum and 3% Bismuth Tribromophenate. Dynarex Xeroform Petrolatum Dressing use is 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.

Gauze saturated with a moist or wet ointment is normally used to maintain a healthy and hydrated wound bed so that wounds can heal effectively and dressings can be changed without causing unnecessary discomfort. One of the substances the Dynarex Xeroform Petrolatum Dressing is saturated with is the petroleum-derived, gelatinous substance petrolatum.

When applied to a non-draining or lightly draining wound, Dynarex Xeroform Petrolatum Dressing provides a moist environment, conducive to wound healing.

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14. **Description of Specific Standards Used for the Dynarex Xeroform Petrolatum Dressing Which Describe the Physical Properties of the dressing.**

Standard methods for the manufacture of the Dynarex Xeroform Petrolatum Dressing are utilized by the manufacturer. The Certificates of Analysis showing the standards / testing referenced by the manufacturer which would define the physical properties of the petrolatum and 3% bismuth tribromophenate used in the device manufacturing are attached.

15. **Quality Assurance Testing**

The quality system is operated and maintained under FDA/QSR CFR21 Part 820 and ISO 13485 guidelines. Documented testing procedures are in place. Initial inspection has visual characteristics such as appearance of mixed ingredients, coating, cutting edges and size and heat sealing testing. Final inspection includes these tests and additional weight and count inspection testing on the finished device to demonstrate the device meets its defined specifications. Dynarex Corporation additionally inspects the product upon arrival for final release.

Standards used:

AAMI/ANSI/ISO 10993-1 Biological Evaluation of Medical Devices – Part 1
Evaluation and Testing Parts 3, 4, 5, 10, 11 2009 (R) 2013

ISO 11137-2 Sterilization of Healthcare Products – Radiation – Part 2 – Dose Method 1 2013

16. **Standard Operating Procedures as Applied to the Manufacture of the Dynarex Xeroform Petrolatum Dressing**

Standard operating procedures (SOP's) are in place for the manufacturing and assembly portions of the manufacturing such as Machine Set-Up, Process Control, Initial Testing, On-line visual testing (Roaming Inspector) and final inspection.

17. **Sterilization Validation / Routine Processing**

The dressing is a sterile device via gamma radiation per ISO 11137-2: 2013 to a $10^6$ SAL.

18. **Dynarex Xeroform Petrolatum Dressing Biocompatibility**

Biocompatibility Testing Matrix: Surface Device, Prolonged [≤ 24 hrs to ≤30 days], Breached / Compromised.

Biocompatibility
The device meets all of the requirements, as applicable, to
ISO 10993-3: 2014 Genotoxicity
ISO 10993-4: 2006 / ASTM F756: Hemolysis,
ISO 10993-5:2009 Cytotoxicity,
ISO 10993-10: 2010 Skin Sensitization and Primary Skin Irritation,
ISO 10993-11: 2006 Systemic Toxicity,

19. **Shelf Life / Expiration Dating**

Dynarex is claiming a 3 year shelf life / expiration dating.

20. **Labeling / Special Labeling Claims**

Labeling samples for the device pouch, box and insert are attached.

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It is understood from the predicate devices 510k letter of substantial equivalence that the Dynarex Xeroform Petrolatum Dressing product has the following limitations;

1. This device may not be labeled for use on 3rd degree burns.
2. This device may not be labeled as having an accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

**Table 1**

TABLE OF COMPARISON

| CHARACTERISTIC | | APPLICANT DEVICE DYNAREX XEROFORM PETROLATUM DRESSING | PREDICATE DEVICE KENDALL XEROFORM PETROLATUM DRESSING |
|---|---|---|---|
| Indication for Use | | 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. | 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 where mild medication and deodorization are desired. |
| Device Materials | Substrate | Cotton Gauze | Cotton Gauze |
| | Material 1 | 3% Bismuth Tribromophenate | 3% Bismuth Tribromophenate |
| | Material 2 | Petrolatum | Petrolatum |
| Single Use | | Yes | Yes |
| Color | | Yellowish | Yellowish |
| Dimensions | | 1x8"/2x2"/4x4"/5x9" | 1x8"/2x2"/4x4"/5x9"/4"x3yds |
| Sterility | | Sterile - ISO 11137-2: 2013 to a $10^6$ SAL | Sterile ISO 11137-2: 2013 to a $10^6$ SAL |
| Pouch Packaging | | PET / ALPET / PE | Metalized chevron pouches |

In summary, Dynarex Xeroform Petrolatum Dressing meets the same biocompatibility requirements per ISO 10993-3, ISO 10993-4, ISO 10993-5, ISO 10993-10 and ISO 10993-11 as our predicate device. Also, it's physical and performance meets requirements of it's pre-defined acceptance criteria for intended uses as the predicate device. All dressings are sterilized by radiation using conditions validated following ISO 11137-2: 2013 to a $10^6$ SAL as the predicate device.

**21. Substantial Equivalent Statement**

Based on the comparisons stated above of the intended use, design, materials and performance, our Dynarex Xeroform Petrolatum Dressing is substantially equivalent to its predicate device.