November 17, 2023

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

Re: K230190
Trade/Device Name: Polyver Silver Alginate Dressing (Prescription and OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 21, 2023
Received: February 21, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Yu-chieh Chiu -S

Yu-Chieh Chiu, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230190

Device Name
Polyver Silver Alginate Dressing (Prescription and OTC)

Indications for Use *(Describe)*
Prescription Use:
"Polyver Silver Alginate Dressing" is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

OTC Use:
First aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns

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:

This510(K) Summary is being submitted
in accordance with the requirements of 21CFR 807.92

1.0 Submitter & Foreign Manufacture 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

2.0 Contact Person

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

3.0 Date of Summary: November 15, 2023

4.0 Device Name:

Trade Name:	Polyver Silver Alginate Dressing (Prescription and OTC)
Common Name:	Silver Alginate Dressing
Device Common Name:	Dressing, wound, Drug
Product Code:	FRO
Classification:	Unclassified
Review Panel:	General & Plastic Surgery

5.0 Predicate Device Information:

(1) K041316, "Silver Alginate II Dressing", manufactured by "Advanced Medical Solutions Ltd", located in Winsford, Cheshire, United Kingdom

(2) K143335, "Roosin Silver Calcium Alginate Dressing/Roosin Antibacterial Calcium Alginate Dressing", manufactured by "Roosin Medical Co., Ltd." located in Taizhou, Jiangsu Province, China

6.0 Device description:

"Polyver Silver Alginate Dressing (Prescription and OTC)" is a sterile, non-woven pad composed of a high G (guluronic acid) calcium alginate and silver particles, which releases silver ions within the dressing and absorbs wound exudate. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment.

The dressing may be used for periods up to 7 days, and can be removed intact during dressing changes

The alginate material consists of silver that controls bacterial growth within the dressing. Based on in vitro laboratory testing, the silver has been shown to protect the dressing against Gram positive andGram negative bacteria, such as *Escherichia coli, Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis*.

Based on in vitro testing, the silver effectively reduces bacterial growth within the dressing for up to seven days. Use of this device should be discontinued completely after 7 days.

No clinical benefit has been demonstrated regarding the effectiveness of silver in the subject dressing.

The dressing has an off-white appearance and is available in the form of pad and in various different sizes packaged in pouches. All dressings have the exactly the same material, chemical, and physical properties and are different only in size.

All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Stability study shows the product has a shelf life of three years.

Product Information:

Antibacterial Agent:	Silver Particles
Target Pathogens:	Gram positive bacteria and Gram negative bacteria.
Spectrum of Activity:	Based on in vitro testing, the silver effectively reduces bacterial growth within the dressing for up to seven days for Gram positive bacteria and Gram negative bacteria, such as *Escherichia coli , Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis.*

Concentration on the device:	Each dressing contains 0.3% w/w silver particles

7.0 Indications for Use:

Prescription Use:

"Polyver Silver Alginate Dressing" is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites

OTC Use:

First aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns

8.0 Comparison to Predicate Devices

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

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

Description	Subject Device	Predicate Device 1 (K041316)	Predicate Device 2 (K143335)
Indication for Use	OTC: First aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns. Prescription "Polyver Silver Alginate Dressing" is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites	Prescription: "Silver Alginate II Dressing" is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites	OTC: First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns. Prescription Roosin Silver Calcium Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites
Prescription/ OTC	Prescription and OTC	Prescription	Prescription and OTC
Mechanism	Silver for antibacterial effect; calcium alginate for exudate absorption and wound care	Silver for antibacterial effect; calcium alginate for exudate absorption and wound care	Silver for antibacterial effect; calcium alginate for exudate absorption and wound care
Design/ Material	Calcium alginate, CMC, and silver	Calcium alginate, CMC, and silver	Calcium alginate and silver

Single Use	Yes	Yes	Yes
Sterile	Sterile	Sterile	Sterile

"Polyver Silver Alginate Dressing (Prescription and OTC)" and its predicate devices are made from same materials, utilize same principles of operation, and have same indications for use.

Biocompatibility was evaluated per ISO 10993-1: 2009, and it was found that the subject device is as biocompatible as the predicate device. The following biocompatibility endpoints were considered:

Cytotoxicity (ISO 10993-5)
Irritation & Sensitization (ISO 10993-10)
Acute Systematic Toxicity (ISO 10993-11)
Subacute Systematic Toxicity (ISO 10993-11)
Material-Mediated Pyrogenicity (ISO 10993-11)
Implantation (ISO 10993-6)

Antibacterial activity was measured following AATCC 100-2004 for total of six clinical relevant bacteria to evaluate antibacterial preservative effectiveness. "Polyver Silver Alginate Dressing (Prescription and OTC)" is effective (>99.99% reduction) for seven days for all six bacteria, such as *Escherichia coli , Klebsiella pneumonia, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis, within the dressing*.

9.0 Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, "Polyver Silver Alginate Dressing (Prescription and OTC)" is substantially equivalent to its predicate devices.