January 11, 2024

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

Re: K231088
Trade/Device Name: Copper Foam Dressing (Prescription and OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 12, 2023
Received: December 13, 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 and Reconstructive 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)*
K231088

Device Name
Copper Foam Dressing (Prescription and OTC)

Indications for Use *(Describe)*
Prescription use indications (Rx-only):
• Partial and full thickness wounds,
• Pressure ulcers (stage I-IV),
• Diabetic ulcers,
• Venous stasis ulcers,
• Arterial ulcers,
• 1st and partial thickness burns,
• Surgical wounds,
• Vascular access or peripheral IV sites,
• Orthopedic external pin sites, and
• Acute wounds such as lacerations, abrasions, and skin tears.

Over-The-Counter (OTC) use indications:
Local management of superficial wounds, minor burns, abrasions and lacerations (tears).

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: K231088

This 510(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: January 6, 2024

4.0 Device Name:

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

5.0 Predicate Device Information:

(1) K180643, "MedCu Antibacterial Wound Dressings with Copper-Oxide (MedCu ABWDs)", manufactured by "MedCu Technologies, Ltd.", located in Herzliya, Israel

6.0 Device description:

"Copper Foam Dressing (Prescription and OTC)" is a sterile, single-use dressing composed of polyurethane and copper oxide particles, which absorbs wound exudate and

releases copper ions in the presence of wound fluid. It also assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

Based on in vitro laboratory testing, the copper has been shown to inhibit bacterial growth within the dressing for up to 7 days.

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:	Copper Particles
Target Pathogens:	Gram positive bacteria, Gram negative bacteria
Spectrum of Activity:	In vitro test results show 7-day antibacterial effect within the dressing 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 2.0% w/w copper

7.0 Indications for Use:

"Copper Foam Dressing (Prescription and OTC)" is indicated for the management of wounds. The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows:

Prescription use indications (Rx-only):

- Partial and full thickness wounds,
- Pressure ulcers (stage I-IV),
- Diabetic ulcers,
- Venous stasis ulcers,
- Arterial ulcers,
- 1st and partial thickness burns,
- Surgical wounds,
- Vascular access or peripheral IV sites,
- Orthopedic external pin sites, and
- Acute wounds such as lacerations, abrasions, and skin tears.

Over-The-Counter (OTC) use indications:

Local management of superficial wounds, minor burns, abrasions and lacerations (tears).

8.0 Comparison to Predicate Devices

"Copper Foam Dressing (Prescription and OTC use)" is compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

(1) K180643, "MedCu Antibacterial Wound Dressings with Copper-Oxide (MedCu ABWDs)", manufactured by "MedCu Technologies, Ltd.", located in Herzliya, Israel

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

Feature	Subject Device	Predicate Device (K180643)
Indication for use	The Copper Foam Dressings are indicated for the management of wounds. The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows: <u>Over-The-Counter(OTC) use indications</u>: Local management of superficial wounds, minor burns, abrasions and lacerations (tears). <u>Prescription use indications (Rx-only):</u> ✓ Partial and full thickness wounds, ✓ pressure ulcers(stage I-IV), ✓ diabetic ulcers, ✓ venous stasis ulcers, ✓ arterial ulcers, ✓ 1st and partial thickness burns, ✓ Surgical wounds, ✓ orthopedic external pinsites, and ✓ acute wounds such as	The MedCu Antibacterial Wound Dressings with Copper-Oxide are indicated for the management of wounds and to provide a physical bacterial barrier. The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows: <u>Over-The-Counter(OTC) use indications:</u> Local management of superficial wounds, minor burns, abrasions and lacerations (tears). <u>Prescription use indications (Rx-only):</u> ✓ Partial and full thickness wounds, ✓ pressure ulcers(stage I-IV), ✓ diabetic ulcers, ✓ venous stasis ulcers, ✓ arterial ulcers, ✓ 1st and 2nd degree burns, ✓ Surgical wounds, ✓ vascular access or peripheral IV

	lacerations, abrasions, and skin tears.	sites, ✓ orthopedic external pinsites, and ✓ acute wounds such as lacerations, abrasions, and skin tears.
Prescription/ OTC	Both prescription and OTC	Both prescription and OTC
Design	✓ Non-adhesive: Single Layer of polyurethane foam with copper oxide ✓ Adhesive: 2-layers: Polyurethane foam with copper oxide, and Polyurethane film with medical adhesive	2- or 3-layer: ✓ Internal layer made of absorbent cellulose and polyester impregnated with copper oxide ✓ one or two external non-adherent nonwoven polypropylene layers containing copper oxide
Dimensions	✓ Adhesive: 2 cm x 7.2 cm, 3.8 cm x 7.5 cm,5 cmx5cm, 5 cm x 13cm, 10 cm x 10cm, 20 cm x 20 cm ✓ Non-adhesive: 5 cm x 5 cm, 5 cm x 13 cm, 10 cm x 10 cm, 20 cm × 20 cm	10 cm x 10 cm, 5 cm x 5 cm
Material	Copper oxide, polyurethane foam, medical adhesive	Copper oxide, polypropylene, polyester, Cellulose, medical adhesive
Antibacterial agent	Copper oxide	Copper oxide
Technology	Wound dressing is impregnated with copper oxide	Wound dressing is impregnated with copper oxide
Principle of operation	Antibacterial effect is achieved via the released copper ions within the dressing in moist environment	Antibacterial effect is achieved via the released copper ions within the dressing in moist environment
Adhesive/ Non-adhesive	Both	Both
Antibacterial Effectiveness	Up to 7 days	Up to 7 days
Absorbency	> 500%	> 500%
Sterilization	Sterile by radiation	Sterile by EtO
Single Use	Yes	Yes

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

Per FDA's guidance document entitled “Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'”, as well as ISO 10993-1: 2018, the following biocompatibility endpoints are considered:

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

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

Antibacterial activity was measured following AATCC 100-2004 for clinical relevant bacteria to evaluate antibacterial effectiveness. “Copper Foam Dressing (Prescription and OTC)” has been shown to be effective for antibacterial effect against Gram positive and Gram negative bacteria that lasts for seven days within the dressing.

9.0 Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, “Copper Foam Dressing (Prescription and OTC)” is substantially equivalent to its predicate devices.