July 18, 2024

Kericure Inc.
% Mehdi Kazemzadeh-Narbat
Associate Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC.
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K212521
Trade/Device Name: Field Shield Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 11, 2024
Received: January 11, 2024

Dear Mehdi Kazemzadeh-Narbat:

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 and Part 809 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,

Julie A. Morabito -S

Julie A. Morabito, PhD
Assistant Director
Office of Surgical and Infecious Diseases Control Devices (OHT4)

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K212521

Device Name
Field Shield® Wound Dressing

Indications for Use *(Describe)*
The Field Shield® Wound Dressing is indicated for the following:

Rx
Management of partial and full thickness wounds including stage I - IV pressure ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, Diabetic skin ulcers, 1st and 2nd degree burns, post-surgical incisions, graft sites, lacerations, skin tears, cuts and abrasions.

OTC
Management of minor wounds including minor cuts, abrasions, lacerations and 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

| | |
|---|---|
| **Submitted by** | KeriCure Medical<br>Kerriann Greenhalgh, PhD<br>CEO, CSO<br>855-888-5374 |
| **Prepared by/Contact** | Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA Associate Director, Regulatory Affairs, MCRA, LLC<br>1050 K Street NW, Suite 1000, Washington, DC 20001<br>Office: 202.552.6011<br>mkazemzadeh@mcra.com |
| **Date Prepared** | July 16, 2024 |
| **Device Trade Name** | Field Shield Wound Dressing |
| **Device Common Name** | Hydrogel Wound Dressing |
| **Classification** | Wound Dressing with Drug or Biologic |
| **Product Code, Class** | FRO, Unclassified |
| **Primary Predicate** | ASAP Antibacterial Silver Wound Dressing Gel (K092826) |
| **Reference Predicates** | Amerigel Wound Dressing PLUS (K092086)<br>Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel (K150799)<br>Ionsil Gel (K132326)<br>AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B (K083103)<br>ASAP OTC Wound Dressing Gel (K140483)<br>Silverlon Wound Contact, Burn Contact Dressing (K190343) |

**Device Description**

The Field Shield Wound Dressing is a spray on hydrogel wound dressing that hydrates, seals and protects dermal injuries to create and maintain a moist wound environment. A moist wound environment is known to be conducive to the wound healing process. It is a hydrophilic system containing a polyacrylate polymer matrix with silver hydrosol and lidocaine. The dressing donates moisture to a wound and maintains a moist environment. When applied to the skin, the liquid device donates moisture to the wound then sets into a thin, pliable, transparent film barrier over the surface of the wound. The film is capable of setting over intact and compromised skin surfaces. The device is intended for use for up to 30 days, with reapplication recommended every 24 to 72 hours. The device contains silver hydrosol that may inhibit the growth of microorganisms such as *Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli*, antibiotic resistant strains of MRSA and VRE, as well as fungi such as *Candida albicans* and *Candida auris* within the dressing. Additionally, the dressing contains lidocaine as a topical anesthetic. Clinical evaluation showed that the Lidocaine can reduce pain within 30 minutes after application; long-term pain reduction has not been evaluated. Field Shield® Wound Dressing is intended for both Prescription and over the counter (OTC) indications for use.

**Indications for Use**

Prescription Indications:

Management of partial and full thickness wounds including stage I - IV pressure ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, Diabetic skin ulcers, 1st and 2nd degree burns, post-surgical incisions, graft sites, lacerations, skin tears, cuts and abrasions.

Over-the-Counter Indications:

Management of minor wounds including minor cuts, abrasions, lacerations and burns.

**Technological Characteristics Compared to Predicate Device**

Field Shield® Wound Dressing is substantially equivalent in technological characteristics including composition, design, performance, route of administration, and intended use to the ASAP Antimicrobial Silver Wound Dressing Gel (K092826) primary predicate and reference predicate devices listed above. The subject device and the predicate devices are all non-sterile, topical hydrogel wound dressings that donate moisture to a wound and are supplied in multiple use plastic containers. All devices are hydrogels that help maintain a moist wound environment to assist with the wound healing process. The subject device and primary predicate device contain the exact same silver hydrosol ingredient, and both have a substantially equivalent mode of operation (pump dispenser). The subject device, Amerigel Wound Dressing Plus and Puracyn® Plus Duo-Care™ Antimicrobial Wound & Skin Hydrogel all provide local pain relief when applied to the skin or wound.

The antimicrobial agents in the proposed Field Shield® Wound Dressing and the predicates have all been shown in laboratory testing to inhibit the growth of microorganisms such *as Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli*, antibiotic resistant strains of MRSA and VRE, as well as fungi such as *Candida albicans* and *Candida auris* within the dressing.

Any technological differences between the subject device and predicates do not raise different questions of safety or effectiveness in comparison to the predicate devices.

**Summary of Performance Testing**

Performance testing has been completed on the device, including Clinical evaluation, Antimicrobial activity testing, Performance testing, Biocompatibility evaluation, Endotoxin testing and Preservative Effectiveness testing, to demonstrate substantial equivalence to the predicate devices. Below is a list of some of the testing completed.

| Testing | Results |
|---|---|
| Clinical Study | Pain Relief provided within 30 minutes of application |
| Guinea Pig Maximization Sensitization Test | Passed (Score 0) |
| Irritation Test | Passed (Score 0) |
| Acute systemic toxicity | Passed (Non-toxic) |
| Material Mediated Pyrogenicity Test | Passed |
| Subacute/Subchronic Toxicity | Passed |
| Implantation | Passed |
| USP<51> Antimicrobial Preservative Effectiveness Test | Passed (met USP 51 and PCPC requirements) |
| USP<51> Modified "Time to Kill" Test | Passed, 99.99% Reduction within 10 minutes of microorganisms including *Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli*, antibiotic resistant strains of MRSA and VRE, as well as fungi such as *Candida albicans* and *Candida auris* |
| Endotoxin Analysis | Passed, <0.5 EU/mL or <20.0 EU/device |

Additionally, a nonclinical study was conducted comparing use of the subject device and standard of care in a wound healing model. There were no device-related adverse events during the study. The results of this study demonstrated that the subject device does not raise different questions of safety and effectiveness and does not significantly increase any concerns of safety or effectiveness in comparison to standard of care and predicate devices.

**Summary of Clinical Testing**

A clinical study was conducted to evaluate the effectiveness of lidocaine in the device when applied to the skin or wound. Subjects were asked to complete an assessment prior to use of the device and within 30 minutes after application of the device, based on a VAS pain score scale. The results of the study determined that the lidocaine within the device has a biological effect on the skin or wound. The data collected established the KeriCure Medical device containing both polyacrylate polymer and lidocaine provides a significant reduction in pain to the treatment area when applied via spray within 30 minutes of application.

**Conclusion**

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are all non-sterile hydrogels with one or more drug ingredient. The data included in this submission demonstrates that Field Shield® Wound Dressing is substantially equivalent to the predicate devices listed above and does not raise different questions of safety or effectiveness in comparison to the predicate devices.