July 16, 2020

KeraNetics
Luke Burnett
CEO and CSO
200 East First Street, Suite 101, Box#4
Winston Salem, North Carolina 27101

Re: K192386
Trade/Device Name: KeraStat Cream
Regulatory Class: Unclassified
Product Code: KGN,
Dated: June 12, 2020
Received: June 15, 2020

Dear Luke Burnett:

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,

Anjana Jain, Ph.D.
Acting 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)*
K192386

Device Name
KeraStat® Cream

Indications for Use *(Describe)*

KeraStat® Cream is intended to maintain a moist wound environment. KeraStat® Cream is indicated for the management of a number of partial thickness skin wounds such as: partial thickness (first and second degree) burns, severe sunburns, superficial injuries, cuts, abrasions, and incisions/surgical wounds. Under the direction of a healthcare professional, KeraStat® Cream also may be used in the management of dry, light, and moderately exuding partial thickness wounds including: pressure (stage I-II) ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites, and grafts.

KeraStat® Cream is not indicated for full thickness or third degree burns. This device will be available by prescription.

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–– KERASTAT® CREAM

Submitter Name: KeraNetics, Inc.
Submitter Address: 200 East First Street, Box #4, Suite 102
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Phone Number: 1.336.202.1307
Fax Number: 1.336.725.0619

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CEO and CSO, KeraNetics, Inc.
Phone Number: 1.336.202.1307
Fax Number: 1.336.725.0619
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Date Prepared: July16, 2020

Device Trade Name: KeraStat® Cream
Device Common Name: Wound Dressing
Classification Number: Unclassified
Product Code: KGN
Product Type Name: Dressing, Wound, Collagen

Predicate Device: KeraStat® Gel
KeraNetics Inc.
K162759
Cleared on June 2, 2017

Reference Device: Biafine®
Valeant Pharmaceuticals
K173549
Cleared on August 13, 2018

Device Description: KeraStat® Cream is a non-sterile, non-implantable wound dressing intended to provide a moist environment in the management of a variety of partial thickness dermal wounds. KeraStat® Cream is provided in a screw top tube for multiple uses. Each tube contains 1 oz (29.6 mL) of KeraStat® Cream, which contains 5% keratin protein incorporated into a cream base.

Statement of Intended Use:

KeraStat® Cream is intended to maintain a moist wound environment. KeraStat® Cream is indicated for management of a number of partial thickness skin wounds such as: partial thickness (first and second degree) burns, severe sunburns, superficial injuries, cuts, abrasions, and incisions/surgical wounds. Under the direction of a healthcare professional, KeraStat® Cream also may be used in the management of dry, light, and moderately exuding partial thickness wounds including: pressure (stage I-II) ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites, and grafts.

KeraStat® Cream is not indicated for full thickness or third degree burns. This device will be available by prescription.

Comparison to the Predicate and Reference Devices:

KeraStat® Cream and the predicate wound dressing, KeraStat® Gel, are both designed for dry, light, and moderately exuding partial thickness wounds. The wound dressings are applied to the wound and function to provide a moist environment for wound management. The operational principles of the subject and predicate device are identical, and they contain identical concentrations and composition of human derived keratin protein. The only differences between KeraStat® Cream and the KeraStat® Gel predicate device are that KeraStat® Cream is provided in an emulsion base, is non-sterile, and is intended for multiple uses.

KeraStat® Cream and the reference wound dressing, Biafine®, have the same intended use to provide a moist environment for wound management including wounds caused by radiation dermatitis. Biafine® has similar technological characteristics as KeraStat® Cream, as both are non-sterile, multi-use cream emulsions composed of a protein/amine, emollients, emulsifiers, thickeners, and preservatives.

Performance Data
Summary of Non-Clinical Tests:

The following testing was performed to demonstrate substantial equivalence:

- Biocompatibility testing:
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Irritation/Intracutaneous reactivity (ISO 10993-10)
  - Acute systemic toxicity (ISO 10993-11)
  - Toxicology Risk Assessment (ISO 10993-17)
  - Chemical Characterization (ISO 10993-18)
  - Implantation Test (ISO 10993-6)
  - Rabbit Pyrogenicity Test (USP Chapter <151>)

- Performance testing:
  - Protein content
  - Viscosity
  - pH
  - Microbial contamination
  - Preservative effectiveness
  - Size-exclusion chromatography (SEC)
  - Stability

Summary of Clinical Tests:

The following human clinical testing was performed:

- Radiation Dermatitis Clinical Study
- Repeat Insult Patch Test
- Skin Prick Test

Testing Summary:

Biocompatibility, performance, and clinical testing support the safety and effectiveness of KeraStat® Cream.

Substantial Equivalence:

KeraStat® Cream has the same intended use, same principles of operation, and similar technological characteristics as the predicate device KeraStat® Gel (K162759). While the subject device differs from the predicate device with respect to its additional components and multi-use design, both devices share the same mode of action in that they provide a moist environment to support wound healing. Any differences in technological characteristics outlined in **Table 1** do not raise new questions about the safety and effectiveness of KeraStat® Cream.

KeraStat® Cream has similar intended use, same principles of operation, and similar technological characteristics as the reference device Biafine® (K173549). Both devices share the same mode of action in that they provide a moist environment to support wound healing, including wounds due to radiation dermatitis. Biafine® has similar technological characteristics as KeraStat® Cream, as both are non-sterile, multi-use cream emulsions composed of a protein/amine, emollients, emulsifiers, thickeners, and preservatives. Any differences in technological characteristics outlined in **Table 1** do not raise new questions about the safety and effectiveness of KeraStat® Cream.

Table 1. Substantial Equivalence Information

Trade Name	**Subject Device: KeraStat® Cream**	**Predicate Device: KeraStat® Gel**	**Reference Device: Biafine®**
510(k) No.		K162759	K173549
Intended Use	Wound dressing for management of partial thickness wounds	Wound dressing for management of partial thickness wounds	Wound dressing for management of partial and full thickness wounds
Indications	Dry, light, and moderately exuding partial thickness wounds such as: first and second degree burns, severe sunburns, superficial injuries, cuts, abrasion, and surgical wounds; may also be used under the guidance of a health care professional in the management of pressure (stage I-II) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites and grafts	Dry, light, and moderately exuding partial thickness wounds such as: first and second degree burns, severe sunburns, superficial injuries, cuts, abrasion, and surgical wounds; may also be used under the guidance of a health care professional in the management of pressure (stage I-II) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts	OTC indications: Management of superficial wounds such as minor cuts, minor scrapes, minor irritations, minor abrasions, minor blisters, 1st degree burns including sunburns, minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. May also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns. Rx Indications: management of full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers, radiation dermatitis, donor sites and 2nd degree burns. May also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.
Mode of Action	Provides a moist environment that is supportive of wound healing	Absorbs exudate and provides a moist environment that is supportive of wound healing	Provides a moist environment that is supportive of wound healing
Technological Characteristics	Mixture of human hair derived keratin proteins in a cream base intended to a create a moist environment and packaged as a non-sterile, multi-use dressing	Mixture of human hair derived keratin proteins intended to absorb exudate and create a moist environment and packaged as sterile single-use dressing	Trolamine/sodium alginate in a cream base intended to a create a moist environment and packaged as a non-sterile, multi-use dressing

Trade Name	**Subject Device: KeraStat® Cream**	**Predicate Device: KeraStat® Gel**	**Reference Device: Biafine®**
510(k) No.		K162759	K173549
Components	Purified water, glycerin, mineral oil, keratin, caprylic triglyceride, dimethicone, sodium polyacrylate, hydrogenated polydecene, trideceth-6, sodium stearoyl glutamate, phenoxyethanol, and ethylhexylglycerin	Purified water, keratin, phenoxyethanol, carbomer, sodium hydroxide, and ethylhexylglycerin	Purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (as potassium salt), propyl paraben (sodium salt), and fragrance
Form of Wound Dressing	Cream	Hydrogel	Cream
Application Method	Topical	Topical	Topical
Sterility	Non-sterile	Sterile	Non-sterile
Number of Uses	Multi-use	Single use	Multi-use
Prescription Use	Yes	Yes	Yes (also OTC)

Conclusion:

KeraStat® Cream demonstrates substantial equivalence to the predicate device, KeraStat® Gel (K162759) and there are not different questions of safety and effectiveness.