DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Keranetics, LLC.
% Kenneth G. Butz, M.Sc.
Associate Director
PPD, LLC.
3900 Paramount Parkway
Morrisville, North Carolina 27560-7200

Re: K162759
Trade/Device Name: Kerastat® Gel
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 27, 2017
Received: April 28, 2017

Dear Kenneth Butz:

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,

Jennifer R. Stevenson -S3

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)*

K162759

Device Name
KeraStat® Gel

Indications for Use *(Describe)*

KeraStat® Gel is intended to provide a moist environment and absorb excess wound exudate. KeraStat® Gel 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 practitioner, KeraStat® Gel 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, donor sites, and grafts.

KeraStat® Gel is not indicated for full thickness (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.

510(k) SUMMARY— KERASTAT® GEL

Submitter Name: KeraNetics, LLC.
Submitter Address: 200 East First Street, Box #4, Suite 102
Winston Salem, NC 27101
Phone Number: 1.336.725.0621
Fax Number: 1.336.725.0619

Contact Person: Kenneth G. Butz
Associate Director, PPD, LLC.
Consultant to KeraNetics, LLC.
Phone Number: 1.919.456.5493
Fax Number: 1.919.882.9754
Email: kenneth.butz@ppdi.com

Date Prepared: April 25, 2017

Device Trade Name: KeraStat® Gel
Device Common Name: Wound Dressing
Device Class: Unclassified, Pre-amendment
Product Code: KGN
Product Type Name: Dressing, Wound, Collagen

Predicate Device(s): Keratec Wound Dressings
Keratec Limited
K080949
Cleared on February 11, 2009

Device Description: KeraStat® Gel is a sterile, non-implantable, water-based gelatinous (hydrogel) wound dressing intended to act as a protective covering in the management of a variety of partial thickness dermal wounds. KeraStat Gel is provided in a sterile, screw top tube for one-time use. Each tube contains 5 mL of KeraStat Gel, which contains 5% keratin protein rehydrated and polymerized in a water base, and is available by prescription from a healthcare professional.

Statement of Intended Use:

KeraStat® Gel is intended to provide a moist environment and absorb excess wound exudate. KeraStat Gel 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 practitioner, KeraStat® Gel 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, donor sites, and grafts.

KeraStat Gel is not indicated for full thickness (third degree) burns. This device will be available by prescription.

Comparison to the Predicate Device:

KeraStat Gel and the predicate wound dressing are both designed for dry, light, and moderately exuding partial thickness wounds. The wound dressings are applied to the wound and function to absorb exudate and provide a moist environment to support wound healing. The operational principles of the subject and predicate devices are identical. The major difference between KeraStat Gel and the predicate device is the source of keratin proteins included in the final device. Table 1 provides a comparison of the subject and predicate devices.

Summary of Non-Clinical Tests:

The following testing was performed to demonstrate substantial equivalence:

- Biocompatibility testing:
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Acute Systemic Toxicity
  - Subacute Systemic Toxicity
  - Pyrogenicity
  - Toxicology Risk Assessment
- Clinical testing:
  - Repeat Insult Patch Test
  - Skin Prick Test
- Other testing:
  - Nucleic acid testing
  - Viral inactivation testing
  - Porcine thermal burn
  - Keratin characterization

Performance Summary:

Biocompatibility and device performance study results support the safety and effectiveness of KeraStat Gel. Biocompatibility, non-clinical, and clinical testing have confirmed that KeraStat Gel functions as intended without adverse effects.

Substantial Equivalence:

KeraStat Gel has the same intended use and principles of operation and similar technological characteristics as Keratec Wound Dressings (K080949). While the subject device differs from the predicate device in the source of keratin protein (human vs. sheep), both devices share the same mode of action in that they absorb exudate and provide a moist environment to support wound healing. KeraStat Gel is as safe and effective and performs as well as the legally marketed predicate device based on an evaluation of biocompatibility, bench, nonclinical, and clinical performance; any differences in technological characteristics outlined in Table 1 do not raise new questions about the safety and effectiveness of KeraStat Gel.

Table 1. Substantial equivalence information.

Trade Name	**Subject Device: KeraStat® Gel**	**Predicate Device: Keratec Wound Dressings**
510(k) No.	K162759	K080949
Intended Use	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, donor sites and grafts	Dry, light, and moderately exuding *partial and full 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-IV*) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts
Mode of Action	Absorbs exudate and provides a moist environment that is supportive of wound healing.	Absorbs exudate and provides a moist environment that is supportive of wound healing.
Technological Characteristics	Mixture of *human hair derived keratin* proteins intended to absorb exudate and create a moist environment packaged as sterile dressing	Mixture of *sheep wool derived keratin* proteins intended to absorb exudate and create a moist environment packaged as sterile dressing
Primary Component	*Human derived keratin* protein	*Animal derived keratin* protein
Additional Components	Purified water, phenoxyethanol, and *ethylhexylglycerin*	Purified water, *lactic acid*, *hydroxyethylcellulose*, *glycerin*, *paraben*, phenoxyethanol, *sorbitol*, and *propylene glycol*
Form of Wound Dressing	Hydrogel	Hydrogel
Application Method	Topical	Topical
Sterility	Sterile	Sterile
Number of Uses	Single use	Single use
Prescription Use	Yes	Yes
Performance Testing	Bench, biocompatibility, nonclinical, and clinical testing	Bench, biocompatibility, nonclinical, and clinical testing