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

February 13, 2017

Exciton Technologies Inc.
Ms. Melanie Ussyk
Director Of Quality Assurance & Regulatory Affairs
10230 Jasper Ave., Suite 4147
Edmonton, Alberta T5J 4P6 Canada

Re: K162508
Trade/Device Name: Kerracel Ag Gelling Fiber Silver Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 9, 2017
Received: January 10, 2017

Dear Ms. Ussyk:

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 -S

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)*
K162508

Device Name
KerraCel Ag Gelling Fiber Silver Dressing

Indications for Use *(Describe)*
Under the supervision of a healthcare professional, KerraGel Ag may be used for management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, first and second degree 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 for KerraCel® Ag

Date of 510(k) Summary Preparation: December 19, 2016

1. Trade (Proprietary) Name

KerraCel® Ag Gelling Fiber Dressing

2. Common Name

Wound or Burn Dressing

3. Contact Information

Contact: Melanie Ussyk
Director, Quality Assurance & Regulatory Affairs

Email: mussyk@excitontech.com
Phone: (780) 248-1281
Fax: (780) 248-5878

Address: **Exciton Technologies Inc.**
Suite 4147-10230 Jasper Avenue
Edmonton, Alberta T5J 4P6
Canada

Contact: Andrew Jackson
Regulatory Medical Device Officer

Email: andrew.jackson@crawfordpharma.com
Phone: +44 (0) 1565 654920
Fax: +44 (0) 1565 654117

Address: **Crawford Healthcare Ltd**
King Edward Court, King Edward Road,
Knutsford, Cheshire, WA16 0BE

4. Device Classification & Panel

General & Plastic Surgery Devices Panel; unclassified.

There have not been prior submissions for KerraCel® Ag submitted to the FDA.

5. Predicate Device(s)

Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K080383) - Primary

Reference Device:
Aquacel® Ag Extra with Hydrofiber® Dressing with Silver and Strengthening Fiber (K121275)

6. Device Description

KerraCel® Ag is a soft, sterile, nonwoven dressing made of sodium carboxymethylcellulose (CMC), cellulose fibers, and silver (0.2mg Ag/ cm^2(1.7 wt/wt%)). The silver in the dressing provides an antibacterial barrier that inhibits bacterial growth in the dressing, as shown *in vitro*, for up to seven (7) days against gram positive and negative bacteria. KerraCel® Ag absorbs high amounts of wound fluid and creates a soft cohesive gel that intimately conforms to the wound surface and maintains a moist wound healing environment. KerraCel® Ag meets endotoxin limit specifications.

7. Indications for Use

Under the supervision of a healthcare professional, KerraCel® Ag may be used for the management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, first and second degree burns.

The Indications for Use statement for KerraCel® Ag is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

8. Summary of Substantial Equivalence

The intended use and directions for use of KerraCel® Ag are equivalent to those of the predicate device, Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K080383). Aquacel® Ag Extra with Hydrofiber® Dressing with Silver and Strengthening Fiber (K121275) has been identified as a reference device since the absorbent properties of the KerraCel® Ag, although similar to K080383, are more comparable to K121275.

The design, manufacturing, and performance are similar to those of the predicate device and do not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

KerraCel® Ag consists of a substrate containing sodium carboxymethycellulose (CMC) needled together with tencel/ cellulose fibers; the substrate is then coated with silver while the predicate, Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing, consists of silver coated CMC fibers needled together with non-silver coated fibers. Importantly, both processes produce oxidized silver ions adherent to the substrate. Differences in the process chemistry do not affect the efficacy or safety of the device as demonstrated by the results of performance and biocompatibility testing.

Both KerraCel® Ag and the predicate are sterilized by gamma irradiation.

b) Summary of Performance Data

The following performance tests were conducted on KerraCel® Ag in comparison to the predicate, Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K080383), and to the reference device, Aquacel® Ag Extra with Hydrofiber® Dressing with Silver and Strengthening Fiber (K121275):

- Silver Content
- Moisture Content
- Absorbency
- Antibacterial Effectiveness
- Tensile Strength (wet & dry)
- Gel Assessment
- Wet out
- Shrinkage
- Lateral Wicking
- Biocompatibility

Biocompatibility Testing

KerraCel® Ag raised no new safety concerns relative to biocompatibility. Assessment was carried out on the final device as per ISO 10993-1:2009 for a surface device; contacting breached or compromised skin, for permanent duration. The device has demonstrated to be safe for its intended use.

KerraCel® Ag was evaluated for:

- Cytotoxicity
- Sensitization
- Irritation
- Genotoxicity

- Systemic Toxicity
- Implantation

Pre-Clinical Studies

A porcine wound healing study was carried out to evaluate the silver cytotoxicity of KerraCel® Ag.

Both KerraCel® Ag and the predicate, Aquacel® Ag (K080383), were evaluated in the study. Six pigs were involved in the study. There were a total of eight 2 x 2 cm, full-thickness wounds created per animal (4 wound sites/side). Left side wound sites were treated with the predicate as a control, and right side wound sites were treated with KerraCel® Ag. Treatments were applied via 3 x 3 cm patches and covered with a barrier dressing on study Days 1, 4, 7 and 11 for all animals (2 and 4-week cohorts) and additional treatments were administered on Days 14, 18, 21 and 24 for 4-week cohort animals.

There were no treatment related abnormal clinical findings during the entire study period. The mean time to complete healing for KerraCel Ag-treated wounds was comparable to Aquacel Ag -treated wounds. Based on the planimetric analysis, the wound areas were similar for wounds of both treatments throughout the study period with no significant differences between treatments at any time points.

Histopathology evaluation revealed that the total healing scores of wounds treated with KerraCel Ag was similar to those treated with the predicate device.

No Clinical Studies were conducted with KerraCel® Ag in comparison to the predicate device.

9. Conclusions

KerraCel® Ag and the predicate Aquacel® Ag are both gelling fiber wound dressings, coated with silver, and intended for the management of wounds. Performance (bench) and Biocompatibility evaluation of KerraCel® Ag; in comparison to that of the predicate device, raises no new concerns regarding safety or effectiveness. The data supports that KerraCel® Ag is substantially equivalent to Aquacel® Ag (K080383) for its intended use.