December 6, 2018

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

Re: K182680
Trade/Device Name: KerraContact Ag Perf Advanced Perforated Silver Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 7, 2018
Received: November 9, 2018

Dear Melanie 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182680

Device Name

KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing

Indications for Use *(Describe)*

The KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing is indicated for use in partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

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.

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510(k) Summary for KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing

510(k) Number: K182680

Date of 510(k) Summary Preparation: September 7, 2018

1. Trade (Proprietary) Name

KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing

2. Common Name

Wound or Burn Dressing

3. Contact Information

Contact: Melanie Ussyk
Director of Quality Assurance & Regulatory Affairs

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

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

4. Device Classification & Panel

Classification: Unclassified

Classification name: Dressing, Wound, Drug

Product Code: FRO

5. Predicate Device(s)

exsalt® T7 Wound Dressing(K113564)(also known as KerraContact® Ag Advanced Silver Wound Dressing)

6. Device Description

Exciton Technologies Inc. has developed the exsalt® technology, a proprietary chemical process, which deposits oxidized silver species onto a non-woven spunlace polyester laminated with gray Delnet® HDPE mesh layers on both sides. Silver in the KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing (KerraContact® Ag Perf) inhibits bacterial growth in the dressing for up to 7 days. The concentration of the silver and oxidized silver species on the dressing is 0.4 mg/ cm^2 (4.5% w/w). The KerraContact® Ag Perf has been shown to be effective *in vitro* against *Staphylococcus aureus*, *Escherichia coli*, *Enterococcus faecalis, Staphylococcus epidermidis, Pseudomonas aeruginosa, and Acinetobacter baumannii.*

KerraContact® Ag Perf meets pyrogen limit specifications.

7. Intended Use

KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing is indicated for use in partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

8. Summary of Substantial Equivalence

The labeled indications and directions for use of the KerraContact® Ag Perf are equivalent to those of the predicate device, KerraContact® Ag Advanced Silver Wound Dressing (K113564). The design, materials, and manufacturing methods are similar to those of the predicate device, KerraContact® Ag Advanced Silver Wound Dressing. The perforations are added to the dressing during the conversion process when the dressings are cut to size; both the subject device and the predicate device are released against the same final specifications.

The new configuration does not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

The KerraContact® Ag Perf consists of 2 outer layers of HDPE with an inner layer of spun lace polyester which are all silver-coated. The skin-contacting materials in both the KerraContact® Ag Perf and the predicate (K113564) are the same.

The perforations in the KerraContact® Ag Perf allow for fluid to wick into and through the dressing with ease; the difference does not impact the dressing performance as demonstrated by the comparative evaluation.

The KerraContact® Ag Perf and the predicate are both sterilized by gamma irradiation.

b) Summary of Performance Data

The following performance tests were conducted on the KerraContact® Ag Perf in comparison to the predicate (K113564):

- Silver Content
  - Total Silver Content
  - Silver Release
  - XRD
  - Qualitative $Ag^{2+/3+}$
- Moisture Content
- pH
- Absorbency
- Anti-bacterial Effectiveness

The predicate device provides a barrier to bacterial penetration whereas the subject device does not. All other performance characteristics of the KerraContact® Ag Perf are equivalent to the predicate.

Biocompatibility

The KerraContact® Ag Perf raised no new safety concerns relating to biocompatibility. Both the subject and predicate devices, in their final finished form, were assessed as surface devices, contacting breached or compromised skin, for a prolonged duration. The device risk assessment identified that the surface characteristics of the KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing, having an additional manufacturing step (perforations), would not illicit a biological response different from the predicate. The chemical components have remained unchanged in comparison to the predicate. Therefore, the biocompatibility data of the predicate device were leveraged to support the biocompatibility of the subject device. Testing performed on the predicate, KerraContact® Ag Advanced Silver Wound Dressing (K113564), showed that it was non-toxic, non-irritant, and did not elicit a sensitization response. KerraContact® Ag Advanced Silver Wound Dressing (K113564) has been marketed since 2011; there have been no complaints or adverse events reported from use as indicated.

Pre/Clinical Studies

No additional pre-clinical or clinical studies were carried out on KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing.

9. Conclusions

KerraContact® Ag Perf and the predicate KerraContact® Ag Advanced Silver Wound Dressing are both surface devices composed of identical materials, coated with silver, and intended for the management of wounds. The risk assessment and performance evaluation raised no new concerns regarding safety or effectiveness. The information supports that KerraContact® Ag Perf Advanced Perforated Silver Wound Dressing is substantially equivalent to KerraContact® Ag Advanced Silver Wound Dressing (K113564).