

510(k) Summary for exsalt® SD7 Wound Dressing with Adhesive Backing

Preparation date: December 1, 2013

1. Trade (Proprietary) Name

exsalt® SD7 Wound Dressing with Adhesive Backing

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 4000-10230 Jasper Avenue
Edmonton, Alberta T5J 4P6
Canada

4. Device Classification & Panel

Unclassified / Surgery

5. Predicate Device(s)

exsalt® SD7 Wound Dressing (K103067)

6. Device Description

Exciton Technologies Inc. has developed the exSALT® technology, a proprietary chemical process, which deposits oxidized silver species onto a substrate; a non-woven polyester with a gray Delnet® HDPE mesh layer thermally laminated to one side (wound contact layer). The pad is backed with a clear polyurethane film with acrylate adhesive to hold the dressing in place. Silver in the exsalt® SD7 Wound Dressing with Adhesive Backing inhibits bacterial growth in the dressing pad. The concentration of the silver and oxidized silver species on the dressing pad is 0.4 mg/cm² (1.8%w/w). The exsalt® SD7 Wound Dressing with Adhesive Backing has been shown to be effective *in vitro* against *Staphylococcus aureus*, *Enterococcus faecalis*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* for up to 7 days.

7. Intended Use

exsalt® SD7 Wound Dressing with Adhesive Backing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second

December 1, 2013

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 of the exsalt® SD7 Wound Dressing with Adhesive Backing are equivalent to those of the predicate device, exsalt® SD7 Wound Dressing (K103067). The directions for use of the exsalt® SD7 Wound Dressing with Adhesive Backing have been modified from the predicate by the removal of the instructions to "Secure with surgical tape or a bandage as appropriate" as the new configuration replaces any need for additional securement. The design, materials, and manufacturing methods of the pad that contacts the wound are the same as those of the predicate device, exsalt® SD7 Wound Dressing (K103067), and therefore do not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

The exsalt® SD7 Wound Dressing with Adhesive Backing consists of a pad constructed of a wound contact layer of HDPE with an inner layer of absorbent polyester which are all silver-coated. The pad has been placed onto a biocompatible clear polyurethane film with acrylate adhesive that allows for securement of the dressing to the skin. The wound-contacting materials in both the exsalt® SD7 Wound Dressing with Adhesive Backing and the predicate are the same.

The exsalt® SD7 Wound Dressing with Adhesive Backing is sterilized by gamma irradiation.

In summary, the change in the exsalt® SD7 Wound Dressing with Adhesive Backing substrate configuration does not raise any concerns related to safety or effectiveness as compared to the predicate device (K103067).

b) Summary of Performance Data

The following performance tests were conducted on the exsalt® SD7 Wound Dressing:

- Silver Content
- Moisture Content
- pH
- Absorbency
- Anti-bacterial Effectiveness; against *Staphylococcus aureus*, *Enterococcus faecalis*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii*
- Silver Release
- Biocompatibility
- X-ray Diffraction

All performance characteristics of the exsalt® SD7 Wound Dressing with Adhesive Backing are the same as the predicate.

The exsalt® SD7 Wound Dressing with Adhesive Backing raised no new safety concerns relating to biocompatibility. Testing performed on the exsalt® SD7 Wound Dressing showed that it was non-toxic, non-irritant, and did not elicit a sensitization response. Testing performed on the polyurethane film with acrylate adhesive showed that it was safe for its intended use based upon the criteria evaluated.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Exciton Technologies Incorporated
Ms. Melanie Ussyk
Suite 4000-10230 Jasper Avenue
Edmonton, Alberta T5J 4P6
Canada

Re: K133775

Trade/Device Name: exsalt[®] SD7 Wound Dressing with Adhesive Backing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2014
Received: February 24, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exciton Technologies Inc.
exsalt® SD7 Wound Dressing with Adhesive Backing

Special 510(k)

exsalt® SD7 Wound Dressing with Adhesive Backing Indications for Use

510(k) Number: K133775

Device Name: exsalt® SD7 Wound Dressing with Adhesive Backing

Indications for Use:

The exsalt® SD7 Wound Dressing with Adhesive Backing 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. The exsalt® SD7 Wound Dressing with Adhesive Backing provides an antibacterial barrier that inhibits bacterial growth in the dressing pad for up to 7 days.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

December 2013