April 4, 2018

DeRoyal Industries, Inc.
Sarah Bennett
Regulatory Affairs Specialist
200 DeBusk Lane
Powell, Tennessee 37849

Re: K173072
Trade/Device Name: Algidex Ag Silver Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 5, 2018
Received: March 5, 2018

Dear Sarah Bennett:

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.

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.

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,

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)*
K173072

Device Name
Algidex Ag Silver Alginate Wound Dressing

Indications for Use *(Describe)*
Abrasions and lacerations, dermal wounds, donor sites, first- and second-degree burns, surgical incisions, vascular access sites, pressure ulcers stages I-IV, stasis ulcers, venous ulcers.

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

Date prepared:	September 28, 2017
510(k) Owner:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849 Owner/Operator #1044833
510(k) Contact:	Sarah Bennett Regulatory Affairs Specialist P: 865-362-6112 F: 865-362-3741 sabennett@deroyal.com
Contract Manufacturer:	DeRoyal Industries, Inc. 1595 Highway 33 South New Tazewell, TN 37825 FDA Establishment # 2320762
Trade Name:	Algidex Ag Silver Alginate Wound Dressing
Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug (Pre-Amendment)
Device Product Code:	FRO
Regulatory Class:	Unclassified
Classification Panel:	General & Plastic Surgery
Predicate Devices:	SilverSite [K041268] (Primary Predicate) Calgitrol Ag Silver Alginate Wound Dressing [K011618]

Device Description
Algidex Ag® silver alginate wound dressings are an antimicrobial barrier for up to three (3) days. The dressings utilize a formulation of ionic silver combined in an alginate and maltodextrin matrix.

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The silver is intended to prevent microbes from passing through the dressing during use. The dressings are offered in two configurations:

1. a paste;
2. a paste applied to a non-adherent polyurethane foam layers in various sizes and shapes;

The device is sterilized by gamma irradiation.

Intended Use
Algidex Ag® silver alginate wound dressings are intended to manage abrasions and lacerations, dermal wounds, donor sites, first- and second-degree burns, surgical incisions, vascular access sites, pressure ulcers stage I-IV, stasis ulcers, and venous ulcers.

Summary of Technological Characteristics

Characteristic	**Algidex Ag Silver Alginate Wound Dressing**	**SilverSite (K041268) (Primary Predicate)**	**Calgitrol Ag Silver Alginate Wound Dressing (K011618)**
Indications for Use	Abrasions and lacerations, dermal wounds, donor sites, first- and second-degree burns, surgical incisions, vascular access sites, pressure ulcers stages I-IV, stasis ulcers, venous ulcers	Pressure ulcers (stages I-IV), dermal lesions (or secreting skin injuries), venous ulcers, stasis ulcers, intended to protect vascular access sites, intramuscular sites, and surgical incisions, 1st and 2nd degree burns, donor sites	Pressure ulcers (stages I-IV), dermal lesions (or secreting skin injuries), venous ulcers, stasis ulcers, 1st and 2nd degree burns, donor sites
Prescription Only	Yes	Yes	Yes
Design	Formulation of ionic silver combined in an alginate and maltodextrin matrix. Placed on the wound in a paste or on a dressing.	Formulation of ionic silver combined in an alginate and maltodextrin matrix. Placed on the wound on a dressing.	Formulation of ionic silver combined in an alginate and maltodextrin matrix. Placed on the wound in a paste or on a dressing.
Materials	Silver alginate paste placed on the wound on its own or on a polyurethane foam	Silver alginate paste placed on the wound on a polyurethane foam	Silver alginate paste placed on the wound on its own or on a polyurethane foam
Microbial Barrier Effectiveness	Effective for 3 days	Effective for 3 days	Effective for 3 days

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Log Reduction	4 log reduction	4 log reduction	4 log reduction
Adherence	Non-adherent	Non-adherent	Non-adherent
Moisture Content	2.46 mL	2.46 mL	2.46 mL
Silver Content	Contains 141 mg silver/100sq cm	Contains 141 mg silver/100sq cm	Contains 141 mg silver/100sq cm
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant	ISO 10993-1 compliant

Summary of Performance Tests

To ensure performance, Algidex Ag was tested when it was developed and originally cleared for the market in 2004, under the brand names SilverSite (K041268) and Calgitrol AG (K011618). Algidex Ag contains the exact same silver alginate and maltodextrin matrix as the predicate devices, and therefore, the testing performed and submitted in the Calgitrol AG 510(k)s continues to support the performance of this device.

The following tests have been performed and are contained within this premarket submission: AATCC 100 test method, antimicrobial barrier testing, and absorbency test. The results indicate the inhibition of microorganism growth within the dressing over the seven-day wear-time of the dressing. The antimicrobial barrier was shown for three days. The absorbency information confirms the dressing absorbs fluid. The proposed device, predicate devices, and other silver-containing devices are substantially equivalent.

Conclusion

The results of performance testing demonstrate that Algidex Ag silver alginate wound dressings are substantially equivalent to the predicate. It is the exact same silver alginate and maltodextrin matrix that was cleared for market in K041268 and K011618. Thus, Algidex Ag is substantially equivalent to the predicate devices.