DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 7, 2015

Laboratoires URGO
Ms. Sophie Fortin
Regulatory Affairs Manager
42 Rue de Longvic
21300 Chenove
France

Re: K143017
Trade/Device Name: Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 7, 2015
Received: July 9, 2015

Dear Ms. Fortin:

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" (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 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 yours,

David Krause -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

Indications for Use

510(k) Number: K143017

Device Name: **Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver**

Indications For Use:

Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver is indicated to manage exuding wounds, especially during the debridement of slough. This includes chronic exuding wounds such as venous stasis ulcers, arterial ulcers, pressure ulcers (stage II-IV), diabetic ulcers; surgical wounds (post-operative, dermatological); partial thickness burns; traumatic wounds; local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided. The dressing also provides an antibiotic barrier for bacterial penetration of the dressing, which may help reduce infection.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Part 5 - 510(k) Summary

Premarket Notification Summary –July 28, 2015

1. Sponsor Information:

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France

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2. Device Name:

Common or Usual Name: Antibacterial Absorbent Wound Dressing with Silver
Proprietary Name: Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver
Classification Name: Unclassified

3. Predicate Devices

Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K063271, K080383), Convatec.

4. Description of Device

Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver is a sterile non-woven highly absorbent pad coated with a silver containing soft-adherent lipido-colloid layer on the dressing/wound interface.
In contact with body fluids (exudates, slough) it forms a gel creating a moist environment, which allows for an easy removal of the dressing with little or no damage to healing tissues, leading to no or minor pain.

It is supplied sterile in an individual pouch.

5. Indications for Use

Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver is indicated to manage exuding wounds, especially during the debridement of slough. This includes chronic exuding wounds such as venous stasis ulcers, arterial ulcers, pressure ulcers (stage II-IV), diabetic ulcers; surgical wounds (post-operative, dermatological); partial thickness burns; traumatic wounds; local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided. The dressing also provides an antibiotic barrier for bacterial penetration of the dressing, which may help reduce infection.

6. Description of Substantial Equivalence:

Substantial Equivalence with Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing is based on technology, indications and safety.

Both products have similar properties & claims, leading to similar indications.

Both products are fiber-based, and contain silver.

Key properties of both dressings are
- Absorption of exudates/body fluids by fibres => gel formation
- Creation of a moist environment to enhance healing
- Antibacterial properties (barrier effect), the dressing provides a barrier against bacterial penetration
- Non-sticking => easy removal of the dressing with little or no damage to healing tissues, leading to no or minor pain
- Conformability to the wound
- Sterility

When compared to Aquacel® Ag Hydrofiber® Wound Dressing, it was demonstrated that Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver have similar properties such as, both are made of sterile fibers, contain silver and have comparable absorption and gelling properties leading to comparable indications for use.
Thus we conclude that Urgoclean Ag Antibacterial Absorbent Wound Dressing with Silver and Aquacel® Ag Hydrofiber® Wound Dressing are substantially equivalent.

In terms of Safety, biocompatibility tests were conducted in accordance with standards ISO 10993 for a product considered as being in prolonged contact with an altered surface (24 hours to 30 days), as long as an overall evaluation of silver dressings tolerance.

From these elements we conclude that Urgoclean Ag, Antibacterial Absorbent Wound Dressing with Silver is as safe as its proposed predicate Aquacel® Ag Hydrofiber® Silver Impregnated Antimicrobial Dressing.