



Food and Drug Administration  
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January 21, 2016

ConvaTec Limited  
Aaron Sibley  
Regulatory Affairs Manager  
First Avenue  
Deeside Industrial Park  
Flintshire, CH5 2NU  
United Kingdom

Re: K152926  
Trade/Device Name: AQUACEL Ag Surgical SP Dressing  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: December 21, 2015  
Received: December 23, 2015

Dear Mr. Sibley:

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 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 (if known)

K152926

Device Name

AQUACEL® Ag Surgical SP Dressing

Indications for Use (Describe)

AQUACEL® Ag Surgical SP may be used for the management of wounds healing by primary intent (e.g., traumatic and elective post operative wounds/incisions) and as an effective barrier to bacterial penetration to help reduce infection.

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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United Kingdom

**510(k) Summary**      **K152926**

**Subject Device:**      AQUACEL™ Ag Surgical SP Dressing

**Date Prepared:**      January 21, 2016

**Applicant:**      ConvaTec Limited  
First Avenue  
Deeside Industrial Park  
Deeside  
Flintshire CH5 2NU  
UK

**Contact:**      Aaron Sibley  
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**Device Trade Name:**      AQUACEL™ Ag Surgical SP Dressing

**Common Name:**      Surgical Cover Dressing

**Classification Name:**      Dressing, Wound, Drug

**Product Code:**      FRO

**Device Class:**      Unclassified

**Predicate Device**

**Device Trade Name:**      AQUACEL™ Ag Surgical Dressing

**Common Name:**      Surgical Cover Dressing

**Classification Name:**      Dressing, Wound, Drug

**Product Code:**      FRO

**Device Class:**      Unclassified

**510(k) Substantial Equivalence:** K091034 - determined substantially equivalent on December 16, 2009

**Device Description:**

AQUACEL™ Ag Surgical SP dressing is a sterile post-operative dressing comprising of an inner (wound contact) non-woven pad composed of Hydrofiber™ technology and ionic silver which is stitch bonded with nylon and elastane yarns. The pad is held in place between a top layer of hydrocolloid adhesive which is bound to an outer polyurethane film and a windowed skin contact layer consisting of polyurethane film sandwiched between one layer of acrylic and one layer of Hydrocolloid contacting the skin.

The outer layer of polyurethane film of AQUACEL™ Ag Surgical SP dressing provides a bacterial and viral barrier to reduce the risk of infection provided the dressing remains intact and there is no leakage.

The highly absorbent central Hydrofiber™ pad absorbs and retains serosanguinous leakage and transforms into a soft gel which maintains a moist environment to support the body's healing process.

The hydrocolloid component of the dressing provides secure, skin friendly adhesion and supports non traumatic removal of the dressing while minimizing damage to the intact surrounding skin.

AQUACEL™ Ag Surgical SP dressing is a waterproof, bacterial and viral barrier dressing which is designed to conform to changes in the wound/incision geometry during body movement and post-operative edema.

The dressing is intended for single use and is provided sterile (via a gamma irradiation process).

This Special 510(k) details the modifications of the predicate device, AQUACEL™ Ag Surgical dressing, which form the AQUACEL™ Ag Surgical SP dressing. These modifications do not alter the intended use or indications for use.

**Indications for Use:**

Under the supervision of a healthcare professional, AQUACEL™ Ag Surgical SP cover dressing may be used for the management of:

Wounds healing by primary intent (e.g. traumatic and elective post operative wounds/incisions) and as an effective barrier to bacterial penetration to help reduce infection.

The indications for use are identical to the predicate device.

**Summary of Technological Characteristics:**

AQUACEL™ Ag Surgical SP dressing has the same intended use and indications for use as the predicate device but has a slimmer profile than the predicate device. This is achieved by replacing an internal hydrocolloid layer of the composite dressing with a thinner acrylic adhesive, and reducing the profile of the two remaining Hydrocolloid layers. The differences in the composition, as detailed below, is explained by the reduction of Hydrocolloid adhesive in the modified device as compared to the predicate device. This necessarily increases the %w/w of the other components overall.

There are no differences in operation and directions for use between AQUACEL™ Ag Surgical SP dressing and the predicate device.

	<b>Predicate Device</b>	<b>Modified Device</b>
	<b>AQUACEL™ Ag Surgical Dressing K091034</b>	<b>AQUACEL™ Ag Surgical SP Dressing</b>
<b>Design</b>	A composite dressing incorporating a central silver containing absorbent pad within a Hydrocolloid adhesive construct with an approximate border thickness of 48 mil.	A composite dressing incorporating a central silver containing absorbent pad within a Hydrocolloid adhesive construct with an approximate border thickness of 27 mil. This reduction is achieved by reducing thickness of two Hydrocolloid layers and replacing an internal Hydrocolloid layer with an acrylic tie layer.
<b>Materials</b>	<b>Layer 1:</b> Polyurethane and Hydrocolloid adhesive <b>Layer 2:</b> Hydrofiber™ pad with 1.2% ionic silver <b>Layer 3:</b> Hydrocolloid adhesive <b>Layer 4:</b> Polyurethane <b>Layer 5:</b> Hydrocolloid adhesive	<b>Layer 1:</b> Polyurethane and Hydrocolloid adhesive <b>Layer 2:</b> Hydrofiber™ pad with 1.2% ionic silver <b>Layer 3:</b> 100% coat acrylic adhesive <b>Layer 4:</b> Polyurethane <b>Layer 5:</b> Hydrocolloid adhesive
<b>Chemical Composition</b>	Approximates: 13.32% Silver Hydrofiber™ (sodium carboxymethylcellulose with silver) 0.71% Nylon yarn 0.89% Elastane (polyurethane) yarn 83.83% proprietary Hydrocolloid adhesive 1.26% Polyurethane Film	Approximates: 19.65% Silver Hydrofiber™ (sodium carboxymethylcellulose with silver) 0.93% Nylon yarn 1.12% Elastane (polyurethane) yarn 71.47% proprietary Hydrocolloid adhesive 3.43% Polyurethane Film 3.4% Acrylic adhesive
<b>Energy Source</b>	No energy sources are utilized	No energy sources are utilized

**Summary of Performance (Non-Clinical Testing) Data:**

Non-clinical testing of the subject device for functional and structural design parameters (such as fluid handling and adhesive properties) has been performed. In this testing, the device’s performance has been found to be comparable to the aforementioned predicate device.

The device has also been biologically evaluated in accordance with the US Food and Drug Administration’s guidance entitled *Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’*, issued May 1, 1995, and has been found safe in such respect for its intended use.

In conclusion, the subject device has been demonstrated as safe and effective and substantially equivalent to the predicate device.