July 20, 2018

ConvaTec Limited
Justin Lovelace
Senior Regulatory Affairs Specialist
First Avenue, Deeside Industrial Park
Flintshire, CH5 2NU, United Kingdom

Re: K173675
Trade/Device Name: AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening Fiber
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 29, 2017
Received: November 30, 2017

Dear Justin Lovelace:

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 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,

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

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)*
K173675

Device Name
AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber

Indications for Use *(Describe)*
For Over-the-Counter Use :

AQUACEL™ Ag+ EXTRA Enhanced Dressing with Silver and Strengthening Fiber may be used for the management of:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional:

AQUACEL™ Ag+ EXTRA Enhanced Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Management of painful wounds;
- Infected 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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Section 5 – 510(k) Summary

Device:	**AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber**
Applicant:	ConvaTec Limited
Contact:	Justin Lovelace Senior Regulatory Affairs Specialist Telephone: 1-336-542-4745 Email: Justin.Lovelace@convatec.com
Date:	July 19, 2018
Trade Name:	**AQUACEL™ Ag+ EXTRA Enhanced Hydrofiber™ Dressing with Silver and Strengthening Fiber**
Classification Name:	Dressing, Wound, Drug
Device Class:	Unclassified
Product Code:	FRO
Predicate Device:	AQUACEL™ Ag EXTRA Hydrofiber™ Dressing, K121275

Device Description

AQUACEL™ Ag+ EXTRA™ Enhanced Hydrofiber™ dressing with Silver and Strengthening Fiber is a soft, sterile dressing made from two layers of 1.2% ionic silver impregnated sodium carboxymethylcellulose fiber with added Ethylenediaminetetraacetic Acid Disodium Salt (EDTA) and Benzethonium Chloride and stitched together with strengthening fibers. The two Hydrofiber™ layers are nominally 77gsm (grams per square meter) weight each. Aquacel Ag+ also includes added Ethylenediaminetetraacetic Acid Disodium Salt (EDTA) and Benzethonium Chloride (BECL).

Based on in vitro testing, the silver preservative in the dressing kills microorganisms held within the dressing (these include bacteria, yeasts and mold) and provides an effective barrier to bacterial penetration of the dressing. This dressing absorbs wound fluid and creates a soft gel that conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). A moist wound environment supports the body's healing process. The silver preservative in the dressing provides an effective barrier to bacterial penetration of the dressing as this may help reduce infection.

Table 1: Device Composition

	Cellulose (Lyocell)		Ag+ Hydrofiber	
	% w/w	g/m^2 of fabric	% w/w	g/m^2 of fabric
Aquacel Ag+ Available in sizes: 5x5cm 10x12cm 15x15cm 20x30cm	17	29	83	144

Indications for Use

Over-the-Counter Use:
AQUACEL™ Ag+ EXTRA Enhanced **Hydrofiber ™** Dressing with Silver and Strengthening Fiber may be used for the management of:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Prescription Use:
Under the supervision of a healthcare professional:
AQUACEL™ Ag+ EXTRA Enhanced **Hydrofiber ™** Dressing with Silver and Strengthening Fiber may be used for
the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Management of painful wounds;
- Infected wounds

The intended use and indications for use are unchanged from the predicate, AQUACEL™ Ag EXTRA Hydrofiber™ Dressing (the cleared Aquacel Ag), K121275.

	Aquacel Ag -K121275- (Predicate Device)	**Aquacel Ag+ (Subject Device)**
Components	Composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver	Composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver with EDTA and benzethonium chloride
Mode of Action	• The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. • The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. • The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed.	• The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. • The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. • The silver preservative in the dressing reduces the growth of microorganisms within the dressing • The silver preservative in the dressing kills wound bacteria held in the dressing and provides an effective barrier to bacterial penetration of the dressing.
Characteristics	• Sterile • Absorbs exudate (including bacteria) or blood • Forms a soft conformable gel • Antimicrobial properties from ionic silver • May require a secondary dressing	• Sterile • Absorbs exudate (including bacteria) or blood • Forms a soft conformable gel • Ionic silver within the dressing functions as a preservative to reduce bacterial growth within the dressing • May require a secondary dressing • EDTA and BeCl improve the preservative action of silver to reduce bacterial growth within the dressing

The materials of construction, function, and fundamental scientific technology of the Aquacel Ag+ remain equivalent to those of the predicate device (K121275).

Biocompatibility Testing:
A biocompatibility evaluation, in accordance with ISO 10993-1:2009, has been conducted and concludes that the dressings have a safe toxicological profile for their intended use. The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Systemic Toxicity
- Genotoxicity
- Subchronic Toxicity
- Toxicological Risk Assessment

Performance Testing – Bench:
Pre-clinical data demonstrate that the Aquacel Ag+ is an effective dressing. The shared technological characteristics with the predicate device (and other Hydrofiber™ dressings) and the corresponding physical properties (as demonstrated *in-vitro* via moisture retention, gelling, absorption, tensile strength and dry fabric properties) make Aquacel Ag+ suitable for the management of a variety of wounds.

The preservative action of silver, EDTA and BeCl within the dressing reduce bacterial growth within the dressing and provide an effective barrier to bacterial penetration of the dressing was confirmed by *in vitro* tests.

- Kill a broad spectrum of micro-organisms within the dressing as demonstrated *in vitro* (tested against Methicillin Resistant *Staphylococcus aureus* (MRSA): USA300 (Heath Protection Agency (HPA) Reference: H045260142), Vancomycin Resistant *Enterococcus faecalis* (NCTC 12201), *Staphylococcus epidermidis* (NCTC 11047), *Streptococcus pyogenes* (NCTC 10872), *Pseudomonas aeruginosa* (NCTC 8506), *Klebsiella pneumoniae* (NCTC13465), *Acinetobacter baumannii* (NCTC 13421), *Escherichia coli* (NCIMB 10544), *Candida krusei* (NCPF 3876), and *Aspergillus brasiliensis* (NCPF 2275)
- The preservative action of silver, EDTA and BeCl within the dressing will continue to reduce bacterial growth within the dressing and provide an effective barrier to bacterial penetration of the dressing for up to 7 days (as demonstrated by *in vitro* studies).

Animal Study:
A study was conducted to evaluate the effect of Aquacel Ag+ on deep partial thickness wound healing using a porcine model. In conclusion, the study authors found no differences in rate of epithelialization, white cell infiltrate or granulation tissue formation between any of the treatment groups. No detrimental effects on healing of wounds managed with Aquacel Ag+ and the predicate device (Aquacel Ag – K121275) as compared to the control were observed. The study demonstrated that both materials examined (Aquacel Ag+ and the predicate Aquacel Ag) did not hinder the wound healing process.

Conclusion:

While establishing substantial equivalence to the predicate device, ConvaTec evaluated the indications for use, materials of construction, technology, and product specifications of the device. The only difference between the two devices is the addition of EDTA and BECL. The results of biocompatibility testing, performance testing and animal testing demonstrate that the Aquacel Ag+ is substantially equivalent to ConvaTec's previously cleared Aquacel Ag (K121275).