

October 16, 2009

K091034
page 1 of 2

Section 5: 510(K) Summary

Device: AQUACEL® Ag Surgical

Applicant: ConvaTec Inc.

Contact: Patricia Kearins
Manager, US Regulatory Affairs
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Date: October 16, 2009

Trade Name: AQUACEL® Ag Surgical

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Predicate Devices: AQUACEL® Ag Hydrofiber® Dressing, K080383
DuoDERM® Extra Thin Dressing, K891696
(currently Class 1, 510(k) exempt)

DEC 16 2009

AQUACEL® Ag Surgical Dressing with Silver is a one piece post-operative dressing comprised of an inner (wound contact) non-woven pad which is held in place by two layers of skin-friendly hydrocolloid adhesive and an outer top layer of polyurethane film. The non-woven pad is comprised of Hydrofiber® dressing and ionic silver stitchbonded with nylon and elastane yarn for dressing extensibility (so the dressing will stretch and be used on flexing joints and limbs) and dressing recovery from extension (after limb movement the dressing will return to its original shape and size without the application of any additional force to the skin).

The one-piece dressing design provides ease of application and removal and provides a waterproof, bacterial, and viral barrier covering to the wound. The benefits provided by this dressing meet the clinical need for improved management of surgical wounds which have wound drainage and are at risk of infection.

AQUACEL® Ag Surgical combines the absorbency/retention properties of AQUACEL® Ag Hydrofiber® Dressing with the gentle skin-friendly properties of DuoDERM® Extra Thin adhesive.

October 16, 2009

AQUACEL® Ag Surgical dressing is a soft, sterile, non-woven pad composed of hydrocolloid fibers. This conformable and highly absorbent dressing absorbs wound fluids, creating a soft gel which maintains a moist environment and supports the body's healing process.

AQUACEL® Ag Surgical dressing is available under the supervision of a healthcare professional and is indicated 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.

Since AQUACEL® Ag Surgical dressing is based on the AQUACEL® Ag Hydrofiber® technology, the safety and effectiveness of AQUACEL® Ag Surgical has been demonstrated by the literature and clinical data provided in previous 510(k)s (i.e., K080383). In summary, a careful and thorough review of the literature suggests that Hydrofiber® dressings have been used safely and effectively in clinical trials for the management of surgical incisions healing with primary intent. All the studies which have been reviewed suggest that, compared to a standard dressing, using a dressing with AQUACEL® leads to less dressing changes.

Thus we believe that, similar to previously cleared Hydrofiber®-based products (reference K080383), AQUACEL® Ag Surgical can be used safely and effectively for the management of wounds healing by primary intent (e.g., traumatic and elective post operative wounds/incisions).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

ConvaTec Inc.
% Ms. Patricia Kearins
Manager, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

DEC 16 2009

Re: K091034
Trade/Device Name: Aquacel[®] Ag Surgical
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 02, 2009
Received: December 03, 2009

Dear Ms. Kearins:

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.

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

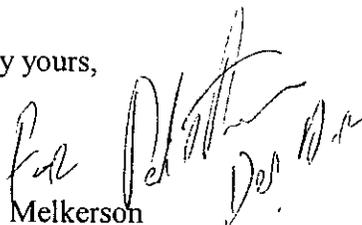
Page 2 - Ms. Patricia Kearins

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/> 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/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications For Use Statement

510(k) Number: K091034

Device Name: AQUACEL® Ag Surgical

Under the supervision of a healthcare professional:
AQUACEL® Ag Surgical 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.

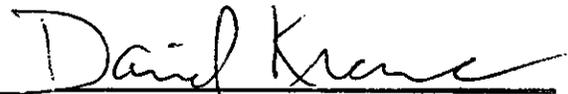
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091034