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510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

SECTION 5: 510(k) SUMMARY

MAY - 2 2008

AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Applicant:

ConvaTec A Division of E. R. Squibb & Sons, LLC 200 Headquarters Park Drive Skillman, New Jersey 08558

Contact:

Marilyn Konicky Associate Director, US and International Regulatory Affairs 908-904-2541 fax: 908-904-2235 email: marilyn.konicky@bms.com

Device:

AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Product Code: FRO

Substantially Equivalent Device: AQUACEL[®] Hydrofiber[®] Wound Dressing K943258, K982116, K063271

AQUACEL[®]Ag Hydrofiber[®] (Silver Impregnated Antimicrobial Dressing) is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

AQUACEL[®] Ag dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions and lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AOUACEL® Ag dressing may be used for more serious wounds such as diabetic foot and leg ulcers, pressure ulcers (partial and full-thickness), surgical wounds or traumatic wounds left to Records processed under FOIA Request # 2015-8493, Released by CDRH or 02-01-2016

510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

heal by secondary intent, and partial thickness burns (second degree), wounds that are prone to bleeding, oncology wounds and management of painful wounds.

AQUACEL® Ag Hydrofiber® Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that, as a protocol of care, may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria provided by AQUACEL® Ag Dressings support the body's healing process and help reduce the risk of wound infection.

A majority of postoperative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of nonadherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

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. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL[®] Ag, which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber® dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintain a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using a Hydrofiber[®] dressing (AQUACEL[®]) leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of Hydrofiber[®] dressings (AQUACEL[®]) in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber® based products (AQUACEL® dressings and AQUACEL® Ag dressings) can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL[®] hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL[®] / Tegaderm[™] to control treatment. AQUACEL[®] / Tegaderm[™]

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510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL® / Tegaderm™ and 98 patients to control) and the results demonstrated that AQUACEL[®] / Tegaderm[™] was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; p<0.00001). Dressing pain score was statistically lower for patients on AQUACEL[®] / Tegaderm[™] dressing compared to control¹ (p<0.001). AQUACEL[®] was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL® hydrofiber dressing group and 31 patients to the control group). Dressing changes were required in (43%) patients in the AQUACEL[®] hydrofiber dressing group compared to (77%) patients in the control group $(p=0.001)^2$. In addition, the use of AQUACEL[®] hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL[®] hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL® hydrofiber dressing potentially limiting mechanical irritation and damage to the wound³. In conclusion, the studies demonstrate that AQUACEL® hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references:

<u>References</u>

- Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL® and Tegaderm[™] versus Cutiplast*. Ann R Coll Surg Engl 2006; 88: 18-22
- 2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber® and central pad dressing. *Int Wound J* 2006; 3; 133-137
- 3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

*Cutiplast is a trademark of Smith & Nephew

Tegaderm[™] is a trademark of 3M Company

AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing are registered trademarks of E.R. Squibb & Sons, L.L.C.

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510(k) Premarket Notification AQUACEL[®] and AOUACEL[®] Ag

Revised April 21, 2008

40-6

SECTION 5: 510(k) SUMMARY

AQUACEL[®] Hydrofiber[®] Wound Dressing

Applicant:

ConvaTec A Division of E. R. Squibb & Sons, LLC 200 Headquarters Park Drive Skillman, New Jersey 08558

Contact:

Marilyn Konicky Associate Director, US and International Regulatory Affairs 908-904-2541 fax: 908-904-2235 email: marilyn.konicky@bms.com

Device:

AQUACEL[®] Hydrofiber[®] Wound Dressing

Classification Name: Dressing, Wound, Hydrophilic

Device Class: Class I

Product Code: NAC

Substantially Equivalent Device: AQUACEL[®] Hydrofiber[®] Wound Dressing

K943258, K982116, K063271

AQUACEL[®]Hydrofiber[®] Wound Dressings are soft, sterile, non-woven pad or ribbon dressings composed of hydrocolloid fibers (sodium carboxymethylcellulose). These conformable and highly absorbent dressings absorb wound fluids and create a soft gel which maintains a moist environment which supports the body's healing process.

AQUACEL[®] dressing is indicated for the management of wounds and can be used overthe-counter for minor wounds such as abrasions, lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AQUACEL® dressing may be used for more serious wounds such as leg ulcers, pressure ulcers (Stages II-IV), diabetic ulcers, surgical wounds, donor sites, second degree burns, wounds that are prone to bleeding and the management of painful wounds.

The Hydrofiber[®] technology in AQUACEL[®] dressings aids in removing necrotic material from the wound without damaging newly formed tissue. AQUACEL® dressings are currently indicated for the management of post-operative surgical wounds and surgical or traumatic wounds that have been left to heal by secondary intention.

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510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

A majority of post-operative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of nonadherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

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. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL[®] which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber[®] dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintains a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using AQUACEL[®] leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of AQUACEL[®] dressings in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber[®] based products can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL[®] hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL[®] / Tegaderm[™] to control treatment. AQUACEL[®] / Tegaderm[™] was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL[®] / Tegaderm[™] and 98 patients to control) and the results demonstrated that AQUACEL[®] / Tegaderm[™] was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; p<0.00001). Dressing pain score was statistically lower for patients on AQUACEL[®] / Tegaderm[™] dressing compared to control¹ (p<0.001). AQUACEL[®] was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL[®] hydrofiber dressing group and 31 patients to the control group). Dressing

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510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

changes were required in (43%) patients in the AQUACEL[®] hydrofiber dressing group compared to (77%) patients in the control group (p=0.001)². In addition, the use of AQUACEL[®] hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL[®] hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL[®] hydrofiber dressing potentially limiting mechanical irritation and damage to the wound³. In conclusion, the studies demonstrate that AQUACEL[®] hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references.

References

- 1. Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL[®] and Tegaderm[™] versus Cutiplast*. *Ann R Coll Surg Engl* 2006; 88: 18-22
- 2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber[®] and central pad dressing. *Int Wound J* 2006; 3; 133-137
- 3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

*Cutiplast is a trademark of Smith & Nephew

Tegaderm[™] is a trademark of 3M Company

AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing are registered trademarks of E.R. Squibb & Sons, L.L.C. Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



MAY - 2 2008

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Convatec, Division of ER Squibb & Sons, LLC % Ms. Marilyn Konicky Associate Director 200 Headquarters Park Drive Skillman, New Jersey 08558

Re: K080383

Trade/Device Name: AOUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing AOUACEL[®] Hydrofiber[®] Wound Dressing Regulatory Class: Unclassified Product Code: FRO, NAC Dated: February 8, 2008 Received: February 12, 2008

Dear Ms. Konicky:

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 such 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); good manufacturing practice requirements as set

Page 2 – Ms. Marilyn Konicky

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark M Miller

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

Enclosure

Records processed under FOIA Request # 2015-8413; Released by CDRH of 0270 42016 of 2 510(k) Premarket Notification

AQUACEL[®] and AQUACEL[®] Ag

Revised May 1, 2008

SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED

510(K) Number (if known): K080383

Device names: AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL[®] Ag Hydrofiber Dressing 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 incisions¹
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites¹
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- Infected Wounds¹

¹Clarified / New Indication, not previously included in this format under K013814 or K063271

Prescription Use <u>X</u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter UseX (21 CFR 801 Subpart C)
	W THIS LINE-CON	TINUE ON ANOTHER PAGE IF NEEDED
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Concurrence of CDRH (Division Signe Officiation (ODE) Division of General, Restorative,		
	and Neuro	logical Devices
	510(k) Nun	nber 16080383

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510(k) Premarket Notification

AQUACEL[®] and AQUACEL[®] Ag

Revised April 17, 2008

SECTION 4: INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K080383

Device name: AQUACEL[®] Hydrofiber[®] Wound Dressing

For Over-the-Counter Use, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for the management of:

- Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- Surgical wounds (post-operative, donor sites, dermatological)
- Partial thickness (second degree) burns
- Traumatic or surgical wounds left to heal by secondary intention such as dehisced surgical incisions¹

- Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹

- Traumatic wounds²
- Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Management of painful wounds

¹ Clarified / New Indication, not previously included in the format under K943258, K982116, or K063271

²Indication re-positioned within Indications for Use statement

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED $\stackrel{\wedge}{\Lambda}$

Concurrence of C	DRH, Office of Device Evaluation (ODE)
(Division Sign-Of Division of Gener and Neurological	al, Restorative,
510(k) Number	16080322

Records processed under FOIA Request # 2015-8413; Released by (DRHO) 02-01-20



200 Headquarters Park Drive Skillman, NJ 08558 908 904-2500

February 14, 2008

FDA CDRH DMC FEB 1 5 2008

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

Received

RE: K080383 Premarket Notification - Addition to Section 20 Bundled 510(k) AQUACEL[®]Hydrofiber[®] Wound Dressing AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Dear Sir/Madam:

The enclosed clinical study report: (b)(4)

(b)(4) was inadvertently omitted from Section 20 - Performance Testing - Clinical in 510(k) K080383 which was received by FDA on February 12, 2008.

Duplicate copies of the omitted clinical study report are enclosed and we respectfully request that they be inserted at the end of Section 20 in the above mentioned 510(k), K080383 per instruction from Marjorie Shulman.

We are sorry for any inconvenience this may cause.

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional and clarified indications and claims for these products. We consider this information to be confidential commercial information and, therefore, exempt from public disclosure.

We trust you will find the enclosed satisfactory; however, should you have any questions, please contact me at (908)-904-2541 or by fax at (908)-904-2235 or via e-mail at marilyn.konicky@bms.com or Patricia Kearins at 908-904-2180 or via e-mail at patricia.kearins@bms.com.

Sincerely,

Marilyn Konicky / pk

Marilyn Konicky Associate Director US and International Regulatory Affairs



Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

Clinical Report, Protocol (b)(4)	ConvaTec
Date: 12/13/2006 -	Page 1 of 45
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CLINICAL STUDY REPORT

(b)(4)

PROTOCOL NO: (b)(4)

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8218

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Services** Food and Drug Administration Memorandum 8-5-68 Date: From: DMC (HFZ-401) Subject: Premarket Notification Number(s): To: Division Director: The attached information has been received by the 510(k) DMC on the above referenced 510(k)submission(s). Since a final decision has been rendered, this record is officially closed. new the attached document and return it to the DMC, with one of the statements checked Please n below Information does not change the status of the 510(k); no other action required by the ; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS. Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN] No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number). CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the **Division of Clinical Laboratory Devices (HFZ-440** Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter) Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm) No response necessary This information should be returned to the DMC within 10 working days from the date of this Memorandum. Reviewed by Date:

,



200 Headquarters Park Drive

Skillman, NJ 08558

USA

www.convatec.com

Tel 908 904 2200

August 1, 2008

Marjorie G. Shulman Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation (HFZ-404) 9200 Corporate Boulevard Rockville, MD 20850

FDA CDRH DMC AUG **0** 5 2008 Received

Dear Ms. Shulman:

This letter serves as notification to the Food and Drug Administration that the ownership of the following 510(k) has been transferred from ConvaTec, a Division of E.R. Squibb & Sons, L.L.C. to ConvaTec Inc.:

K080383- AQUACEL[®] and AQUACEL[®] Ag Hydrofiber[®] Wound Dressing Product Code: NAC - Class 1 and FRO - Unclassified FDA Clearance Date: 05/02/2008

On May 2, 2008, Bristol-Myers Squibb Company signed a definitive agreement to sell certain stock and assets comprising its ConvaTec business (ConvaTec, a Division of E.R. Squibb & Sons, L.L.C.) to Nordic Capital Fund VII and Avista Capital Partners. This corporate transaction was completed on August 1, 2008. The new company will trade under the name of ConvaTec Inc.; will continue to manufacture and sell all of the same products/brands and will continue to operate out of the existing ConvaTec headquarters and manufacturing locations. ConvaTec products will continue to be made according to the same specifications and under the same accredited quality standards (ISO and Quality Systems Regulations).

If you have any questions or need additional information, please contact (b)(4) (b)(4) (b) Thank you.

Sincerely,

(b)(6) (b)(6)

Manager, US Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 2 5 2008

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

ConvaTec, Inc. 200 Headquarters Park Drive Skillman, NJ 08558

Re: See Enclosed List

Dear Ms(b)(6)

We have reviewed your letter, dated August 1, 2008 stating that the rights to the above referenced premarket notifications (510(k)s) have been transferred. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Consequently, we cannot change the name of the original 510(k) submitter in our database. Please note, as per 21 CFR 807.85(b), a firm may not **both** manufacture and distribute a device under their own name without having their own 510(k).

We suggest that information showing the transfer of the 510(k)s and their current ownership should be maintained in the company's files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (240) 276- 0100 if you have any questions on what information we expect to be maintained in your files.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Heather S. Rosecrans Director, Premarket Notification Section Program Operations Staff Office of Device Evaluation Center for Devices and Radiological Health

cc: ConvaTec, A Division of E.R. Squibb & Sons 200 Headquarters Park Drive Skillman, NJ 08558

Enclosed List

K013814 – AQUACEL® Ag Hydrofiber Wound Dressing

K071763 – AMADEUS Adaptive Compression Therapy

K080383 – AQUACEL® and AQUACEL® Ag Hydrofiber Wound Dressing

K063271 – AQUACEL® AND AQUACEL® Ag Hydrofiber Wound Dressing

K810200 – Optipore Sponge

K811240 – Gentle Touch Post Op Kits with Loop Ostomy Rod and ConvaTec Loop Ostomy Rod

K832299 - Irrigator with Stoma Cone (Visi-Flow) and Irrigator Starter Set

K032734 – Flexi-Seal FMS

K811160 – Irrigation Sleeves (Visi-Flow)

4

DEPARTMENT OF HEALTH & HUMAN SERVICES



Public Health Service

MAY - 2 2008

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Convatec, Division of ER Squibb & Sons, LLC % Ms. Marilyn Konicky Associate Director 200 Headquarters Park Drive Skillman, New Jersey 08558

Re: K080383

Trade/Device Name: AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing AQUACEL[®] Hydrofiber[®] Wound Dressing

Regulatory Class: Unclassified Product Code: FRO, NAC Dated: February 8, 2008 Received: February 12, 2008

Dear Ms. Konicky:

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 such 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 <u>Federal Register</u>.

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); good manufacturing practice requirements as set

Page 2 – Ms. Marilyn Konicky

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Milken

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

Enclosure

AQUACEL[®] and AQUACEL[®] Ag

Revised May 1, 2008

SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED

510(K) Number (if known): K080383

Device names: AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

For Over-the-Counter Use, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL[®] Ag Hydrofiber Dressing 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 incisions¹
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites¹
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- Infected Wounds¹

¹Clarified / New Indication, not previously included in this format under K013814 or K063271

Prescription Use (Part 21 CFR 801 Su	<u>X</u> bpart D)	AND/OR	Over-the-Counter UseX (21 CFR 801 Subpart C)
PLEASE DO NOT	WRITE BELOW TH	HS LINE-CONT	TINUE ON ANOTHER PAGE IF NEEDED
. (Concurrence of CDR	Division of (SignEOfficiation (ODE) General, Restorative,
		and Neurolo	logical Devices
		510(k) Num	nber 16080383

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Premarket Notification

AQUACEL[®] and AQUACEL[®] Ag

Revised April 17, 2008

SECTION 4: INDICATIONS FOR USE STATEMEN

510(K) Number (if known): K080383

Device name: AQUACEL[®] Hydrofiber[®] Wound Dressing

For Over-the-Counter Use, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers

Surgical wounds (post-operative, donor sites, dermatological)

Partial thickness (second degree) burns

Traumatic or surgical wounds left to heal by secondary intention such as dehisced surgical incisions¹

Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹

Traumatic wounds²

Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites

Management of painful wounds

¹ Clarified / New Indication, not previously included in the format under K943258, K982116, or K063271

²Indication re-positioned within Indications for Use statement

Prescription Use _ AND/OR X (Part 21 CFR 801 Subpart D)

Over-the-Counter Use _ (21 CFR 801 Subpart C)

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

Concurrence of C	DRH, Office of Device Evaluation (ODE)
(Division Sign-O	ff)
Division of Gener	
and Neurological	· · · ·
510(k) Number	16080382

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

> Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Mail Center (HFZ-401) 9200 Corporate Blvd. Rockville, Maryland 20850

> > DRESSING

February 13, 2008

CONVATEC, A DIVISION OF E.R. SQUIBB 510(k) Number: K080383200 HEADQUARTERS PARK DR.Received:SKILLMAN, NJ 08558Product:ATTN: MARILYN KONICKYWOUND DRESSING AND
AG HYDROFIBER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796t8#18

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form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

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Sincerely yours,

Marjorie Shulman Supervisory Consumer Safety Officer Office of Device Evaluation Center for Devices and Radiological Health

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510(k) PREMARKET NOTIFICATION

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AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag Hydrofiber[®] Dressing

(Silver Impregnated Antimicrobial Dressing)

Additional / Clarified Indications

Dated: February 8, 2008

ConvaTec, a Division of E.R. Squibb & Sons, L.L.C. 200 Headquarters Park Drive Skillman, NJ 08558

> FDA CDRH DMC FEB 1 2 2008

> > Received



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Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification February 8, 2008 AQUACEL® and AQUACEL® Ag

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) (b)(4) Write the Payment Identification number on your check.
	n or supplement subject to fees. The following actions must be taken
1. Electronically submits the completed Cover Sheet to the Food a	nd Drug Administration (FDA) before payment is sent.
	k made payable to the Food and Drug Administration. Remember that
 Mail Check and Cover Sheet to the US Bank Lock Box, FDA Acc should payment be submitted with the application.) 	count, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case
 If you prefer to send a check by a courier, the courier may delive 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: The 418-4821 if you have any questions concerning courier delivery.) 	er the check and Cover Sheet to: US Bank, Attn: Government Lockbox his address is for courier delivery only. Contact the US Bank at 314- .)
 For Wire Transfer Payment Procedures, please refer to the MDL http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsi 	ible for paying all fees associated with wire transfer.
Include a copy of the complete Cover Sheet in volume one of the CDRH Document Mail Center.	e application when submitting to the FDA at either the CBER or
1. COMPANY NAME AND ADDRESS (include name, street	2. CONTACT NAME
address, city state, country, and post office code)	Marilyn Konicky
, , , , , , , , , , , , , , , , , , ,	2.1 E-MAIL ADDRESS
	marilyn.konicky@bms.com
200 HEADQUARTERS PARK DRIVE SKILLMAN NJ 08558 US	2.2 TELEPHONE NUMBER (include Area code) 908-904-2541
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)
136121983	908-904-2235
Select an application type: [X] Premarket notification(510(k)); except for third party [] 513(g) Request for information [] Biologics License Application (BLA) [] Premarket Approval Application (PMA) [] Modular PMA [] Product Development Protocol (PDP) [] Premarket Report (PMR) [] Annual Fee for Periodic Reporting (APR) [] 30-Day Notice 4. ARE YOU A SMALL BUSINESS? (See the instructions for more i [] YES, 1 meet the small business criteria and have submitted the re qualifying documents to FDA.	
4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF TH APPLICABLE EXCEPTION.	
[] This application is the first PMA submitted by a qualified small bus including any affiliates, parents, and partner firms	conditions of use for a pediatric population
[] This biologics application is submitted under section 351 of the Pu Health Service Act for a product licensed for further manufacturing us	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FC PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION O subject to the fee that applies for an original premarket approval appl	OF USE FOR ANY ADULT POPULATION? (If so, the application is
[] YES [X] NO	
 USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREM. (b)(4) 	ARKET APPLICATION 16-Nov-2007
form FDA 3601 (01/2007)	
"Close Winc	dow" Print Cover sheet

510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				OMB No. 9010-0120 Expiration Date: August 31, 2010.			⊢0120 ∋: August 31, 2010.
CDRH PREMARKET REVIEW SUBMISSION Date of Submission User Fee Payment ID Number			CUVER	SHEET See OMB Statement on page 5. FDA Submission Document Number (if known)			
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SECTION A		TYPE OF S		N			
PMA Original Submission Premarket Report Modular Submission Amendment Report Report Amendment Licensing Agreement	PMA & HDE Supplement Regular (180 day) Special Panel Track (PMA Only) 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Amendment to PMA &HDE Supplement Other	PDP Original PDP Notice of Completion Amendment to PDP		510(k) ☐ Original Submission: ☐ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party		piete	Meeting Pre-510(K) Meeting Pre-IDE Meeting Pre-PMA Meeting Pre-PDP Meeting Day 100 Meeting Agreement Meeting Determination Meeting Other (specify):
IDE	Humanitarian Device	Class II Exemption Petition		Evaluation of Automatic			Other Submission
Original Submission Amendment Supplement	Exemption (HDE) Original Submission Amendment Supplement Report Report Amendment	Original Submission Additional Information		Class III Designation (De Novo) Original Submission Additional Information			 513(g) Other (describe submission):
Have you used or cited Sta	ndards in your submission?	Yes 2	No (#	Yes, please (complete Sectio	n I, Page 5	i)
			Establishment Registration Number (if known) 2243969				
Division Name (<i>if applicable</i>) division of E.R. Squibb & Sons, L.L.C.			Phone Number (including area code) (908) 904-2541				
Street Address 200 Headquarters Park Drive		FAX Number (including area code) (908) 904-2235					
City Skillman		State / Province New Jersey		ZIP/Postal Coo 08558	le	Country USA	
Contact Name Marilyn Konicky							1
Contact Title Associate Director, US and International Regulatory Affairs			Contact E-mail Address marilyn.konicky@bms.com				
SECTION C	APPLICATION CORRE	SPONDENT (e.	g., consulta	ant, if diffe	rent from abo	ve)	
Company / Institution Name	e					·	
Division Name (if applicable)		Phone Number (including area code) (')					
Street Address		FAX Number (including area code) ()					
City		State / Provi	nce	ZIP/Postal Co	le	Country	
Contact Name							
Contact Title	Contact Title			Contact E-mail Address			
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FORM FDA 3514 (9/07)

PAGE 1 of 5 PAGES PSC Graphics: (301) 443-2454 EF

February 8, 2008

ConvaTec, A Division of E.R. Squibb and Sons I.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 119

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February 8, 2008

SECTION D1 RE	ASON FOR APPLICATION - PMA, PDP, OR	HDE
Withdrawal Additional or Expanded Indications Request for Extension Post-approval Study Protocol Request for Applicant Hold Request for Removal of Applicant Hold Request to Remove or Add Manufacturing Site	Change in design, component, or specification: Software / Hardware Color Additive Material Specifications Other (specify below)	Location change: Manufacturer Sterilizer Packager
Process change: Manufacturing Sterilization Packaging Other (specify below) Response to FDA correspondence:	Labeling change: Indications Instructions Performance Shelf Life Trade Name Other (specify below)	Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment Change in Ownership Change in Correspondent Change of Applicant Address
Other Reason (specify):	1	
SECTION D2 New Device New Indication Addition of Institution Expansion / Extension of Study IRB Certification Termination of Study Withdrawal of Application Unanticipated Adverse Effect Notification of Emergency Use Compassionate Use Request Treatment IDE Continued Access	REASON FOR APPLICATION - IDE Change in: Correspondent / Applicant Design / Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor Current Investigator Annual Progress Report Site Waiver Report Final	Repose to FDA Letter Concerning: Conditional Approval Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting Request Hearing
Other Reason (specify):	1	- · · · · · · · · · · · · · · · · · · ·
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SECTION D3	REASON FOR SUBMISSION - 510(k)	
New Device	Additional or Expanded Indications	Change in Technology
Other Reason (<i>specify):</i> NOTE: This is a bundled submission - sec al.	so the Submission Cover Sheet for AQUACEL Ag	Hydrofiber Wound Dressing

PAGE 2 of 5 PAGES

ConvaTec, A Division of F.R. Squibb and Sons, LLC. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 120

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510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

February 8, 2008

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	K943258			1	ConvaTec Hydroc	olloid Wound	Dressing		1	Conva	Tec, div. of I	E.R. Squib	b & Sons, LI
	K982116			2	AQUACEL Hydro	fiber Wound	Dressing		2	Conva	Tec, div. of I	E.R. Squib	b & Sons, LI
	K063271			3	AQUACEL & AQ Dressings (bundled		Wound		3	Conva	Tec, div. of I	E.R. Squib	b & Sons, LI
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FORM FDA 3514 (9/07)

PAGE 3 of 5 PAGES

ConvaTec, A Division of F.R. Squibb and Sons, I.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 2

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

AQUACEL® and AQUACEL® Ag

Add:::Submission of this information does and affect the need to submit a 2891 FDA Document Number (if known) SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION	Notice Sublimition interfactuation does in our sector in preside or submit a 2001 SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION Criginal Conjinal Conjinal Contract Manufacturer Contract Manufacturer Repackager / Relabeler Contract Manufacturer Repackager / Relabeler Contract Manufacturer Repackager / Relabeler Company / Institution Nome Eablishment Registration Number Division Name (If applicable) Phone Number (Including area code) Street Address Eablishment Registration Number Street Address Contract Table City Street Address Conginal Contract Table Conginal Contract Manufacturer Repackager / Relabeler Contract Manufacturer Confract Name Contract Manufacturer Confract Namufacturer Repackager / Relabeler Original Facility Establishment Identifier (FEI) Number Contract Manufacturer Repackager /	Notice Sublishment Read to subort a 201 SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION Criginal Incluic Exabilishment Mentifor (FE) Number Conginal Incluic Exabilishment Mentifor (FE) Number Contract Manufacturer Repackager / Relabeler Company / Institution Nume Eablishment Registration Number Division Name (# applicable) Phone Number (including area code) Division Name (# applicable) Phone Number (including area code) Street Address Eablishment Registration Number (including area code) Division Name (# applicable) Phone Number (including area code) Street Address Eablishment Registration Number (including area code) Street Address Eablishment Registration Number (including area code) Division Name (# applicable) Phone Number (including area code) Street Address Eablishment Registration Number (including area code) Street Address Eablishment Registration Number (including area code) Division Name (# applicable) Eablishment Registration Number (including area code) Street Address Eablishment Registration Number (including area code) Division Contract Name Contract Sterilizer <t< th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th></t<>											
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UTILIZATION OF STANDARDS

510(k) Premarket Notification

SECTION I

AQUACEL® and AQUACEL® Ag

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement. Standards No. Standards Standards Title Version Date Organization 1 Standards No. Standards Standards Title Version Date Organization 2 Standards No. Standards Standards Title Version Date Organization 3 Standards Standards No. Standards Title Version Date Organization 4 Standards Standards Title Standards No. Date Version Organization 5 Standards No. Standards Standards Title Version Date Organization 6 Standards No. Standards Standards Title Version Date Organization 7 Please include any additional standards to be,cited on a separate page. Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control PAGE 5 of 5 PAGES FORM FDA 3514 (9/07)

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February 8, 2008

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February 8, 2008

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Date of Submission	User Fee Payment ID (b)(4)						Number (if known)
SECTION A	PMA & HDE Supplement	TYPE OF S		N	510(k)	ſ	Meeting
 Original Submission Premarket Report Modular Submission Amendment Report Report Amendment Licensing Agreement 	Regular (180 day) Special - Panel Track (PMA Only) 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Armendment to PMA	Original PDF Notice of Co Amendment	mpletion		al Submission: aditional becial bbreviated (Co. action I, Page 5 onal Informatio	mplete	Pre-510(K) Meeting Pre-IDE Meeting Pre-PMA Meeting Pre-PDP Meeting Day 100 Meeting Agreement Meeting Determination Meeting Other (specify):
, IDE	&HDE Supplement Other Humanitarian Device	Class II Exempt	ion Petition		ation of Autor		Other Submission
Original Submission Amendment Supplement.	Exemption (HDE) Original Submission Amendment Supplement Report Report Report	Original Sub Additional In		🔲 Origin	ss III Designat (De Novo) Ial Submission onal Informatic		 513(g) Other (describe submission):
Have you used or cited Sta	Indards in your submission?	Yes [No (If	Yes, please	complete Sect	tion I, Page	ə 5)
SECTION B	SUB	MITTER, APPLI	CANTORS	PONSOR			•
Company / Institution Nam ConvaTec Division Name (<i>if applicable</i>)	e -	·		ent Registrat	tion Number (if	' known)	
division of E.R. Squibb &			(908)9	04-2541			
Street Address 200 Headquarters Park Dr	ive		FAX Numbe (908) 90		rea code)		
City Skillman			State / Provi New Jersey		ZIP/Postal C 08558	Code	Country USA
Contact Name Marilyn Konicky			. · ·				·
Contact Title Associate Director, US an	d International Regulatory Affa	irs	Contact E-m marilyn.koi		.com		
SECTION C	APPLICATION CORRE	ESPONDENT (e.	g., co <u>nsulta</u>	int, if <u>diffe</u>	rent fr <u>om ab</u>	ove)	
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FORM FDA 3514 (9/07)	- - -		· · · · · · · · · · · · · · · · · · ·				PAGE 1 of 5 PAGES

PAGE 1 of 5 PAGES PSC Graphics: (301) 443-2454 EF

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CTION D1 REA	SON FOR APPLICATION - PMA, PDP, OR	HDE
Withdrawal Additional or Expanded Indications Request for Extension Post-approval Study Protocol Request for Applicant Hold Request for Removal of Applicant Hold Request to Remove or Add Manufacturing Site	 Change in design, component, or specification: Software / Hardware Color Additive Material Specifications Other (specify below) 	Location change: Manufacturer. Sterilizer Packager
Process change: Manufacturing Sterilization Packaging Other (specify below) Response to FDA correspondence:	Labeling change: Indications Performance Shelf Life Trade Name Other (specify below)	Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment Change in Ownership Change in Correspondent Change of Applicant Address
Other Reason (specify):	· · · · · · · · · · · · · · · · · · ·	-L
TION D2	REASON FOR APPLICATION - IDE	
New Device New Indication Addition of Institution Expansion / Extension of Study RB Certification Fermination of Study Withdrawal of Application Jnanticipated Adverse Effect Notification of Emergency Use Compassionate Use Request Freatment IDE Continued Access	Change in: Correspondent / Applicant Design / Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor Report submission: Current Investigator Annual Progress Report Site Waiver Report Final	Repose to FDA Letter Concerning: Conditional Approval Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting Request Hearing
Juner Reason (specny):		· · ·
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TION D3	REASON FOR SUBMISSION - 510(k)	
New Device	Additional or Expanded Indications	Change in Technology
Dther Reason (specify): NOTE: This is a bundled submission - see also	the Submission Cover Sheet for AQUACEL Hyd	rofiber Wound Dressing

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ConvaTec, A Division of E.R. Squibh and Sons LLC Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E Product codes of de	vices to	whic			ONAL INFOR	RMATIO	<u>ON 510</u>	(K) SU	BMI	SSIC	ONS	Summary o	f, or statement concernir
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K013814				3	Absorbent A	ntimicrot	ial Wound	Dressi	ng		3 Conv	aTec, div. of]	E.R. Squibb & Sons, L
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ConvaTec, A Division of E.R. Squibb and Sons I. L. CE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81 Page 10 of 133

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

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		information does not affect the nee shment Registration form.	ed to submit a 2891	FDA Document Number (if kno	
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FORM FDA 3514 (9/07)

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ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81 Page 11 of 133 127

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510(k) Premarket Notification

AQUACEL® and AQUACEL® Ag

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			Food and Drug Administration	· ·	
			CDRH (HFZ-342) 9200 Corporate Blvd.		
			Rockville, MD 20850		

FORM FDA 3514 (9/07)

PAGE 5 of 5 PAGES

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February 8, 2008



200 Headquarters Park Drive Skillman, NJ 08558 908 904-2500

February 8, 2008

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

RE: 510(k) Premarket Notification - Traditional Bundled 510(k) AQUACEL[®]Hydrofiber[®] Wound Dressing AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Dear Sir/Madam:

In accordance with Section 510(k) of the Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, subpart E, this Premarket Notification is being submitted in duplicate by ConvaTec, a Division of E.R. Squibb & Sons, L.L.C.

This is a "bundled 510(k)" for AQUACEL[®] Hydrofiber[®] Wound Dressing and for AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing. Under the FDA guidance document: *Guidance for Industry and FDA Staff Bundling Multiple Devices or Multiple Indications in a Single Submission, June 22, 2007*, we are submitting both premarket notifications in one 510(k) submission.

This bundled 510(k) seeks clearance for additional and clarified indications for AQUACEL[®] Hydrofiber[®] Wound Dressing previously cleared under K943258, K982116 and K063271 and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing previously cleared under K013814 and K063271. Claims to be used in advertising are contained in Section 13 of this application.

Both Hydrofiber[®] products are sterile devices currently marketed by ConvaTec as overthe-counter and prescription medical devices. The only difference between the Hydrofiber[®] dressings is the incorporation of 1.2% ionic silver in the AQUACEL[®] Ag dressings. No significant changes have been made to the Hydrofiber[®] dressings in components or composition and the previously cleared products marketed under AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing – they are the same dressing. ConvaTec has conducted a clinical performance study to provide support for the indication of "management of donor sites". The full study report is included in Section 20 of this application.

AQUACEL[®] Hydrofiber[®] Wound Dressing is classified under 21CFR 878.4018, classification name, *dressing, wound, hydrophilic*, product code is NAC and it is a Class I device. AQUACEL[®] Ag Hydrofiber[®] Silver Impregnated Antimicrobial Dressing has the classification name, *dressing, wound, drug*, product code is FRO and the device is unclassified.

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional and clarified indications and claims for these products. We consider this information to be confidential commercial information and, therefore, exempt from public disclosure.

The Establishment Registration for the manufacturing site at (b)(4)

The Owner/Operator number is: (b)(4)

Two copies of the 510(k) have been submitted in hard copy including the Premarket Review Submission Cover Sheet and a detailed Table of Contents.

Please see the Design and Use of the Device table attached to this letter for the submitted devices as outlined in the 510(k) format document dated August 12, 2005.

We trust you will find the enclosed satisfactory; however, should you have any questions, please contact me at (908)-904-2541 or by fax at (908)-904-2235 or via e-mail at marilyn.konicky@bms.com.

Sincerely. aulyn Konickey

Marilyn Konicky Associate Director US and International Regulatory Affairs

Attachment

MK/pk

Design and Use of the Device

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Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A	X	
Is the device intended for over-the-counter use $(21 \text{ CFR } 807 \text{ subpart C})^{4}$?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?	1	X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

^AA device may be intended for both prescription and over the counter use. If so, the answer to both of these questions is yes.

AQUACEL[®] Hydrofiber[®] is a registered trademark of E.R. Squibb & Sons, L.L.C. AQUACEL[®] Ag Hydrofiber[®] is a registered trademark of E.R. Squibb & Sons, L.L.C.

510(k) PREMARKET NOTIFICATION

AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag Hydrofiber[®] Dressing

(Silver Impregnated Antimicrobial Dressing)

Additional / Clarified Indications Dated: February 8, 2008

ConvaTec, a Division of E.R. Squibb & Sons, L.L.C. 200 Headquarters Park Drive Skillman, NJ 08558

Enclosed is this envelope:

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
- 510(k) Cover Letter with Design and Use of the Device table attached

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification F AQUACEL® and AQUACEL® Ag

m Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4)
A completed Cover Sheet must accompany each original applicatio to properly submit your application and fee payment:	n or supplement subject to fees. The following actions must be taken
1. Electronically submits the completed Cover Sheet to the Food a	nd Drug Administration (FDA) before payment is sent.
	made payable to the Food and Drug Administration. Remember that
 Mail Check and Cover Sheet to the US Bank Lock Box, FDA Ac should payment be submitted with the application.) 	count, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case
 If you prefer to send a check by a courier, the courier may delive 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: TI 418-4821 if you have any questions concerning courier delivery. 	er the check and Cover Sheet to: US Bank, Attn: Government Lockbox his address is for courier delivery only. Contact the US Bank at 314-)
 For Wire Transfer Payment Procedures, please refer to the MDL http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are respons 	ible for paying all fees associated with wire transfer.
 Include a copy of the complete Cover Sheet in volume one of the CDRH Document Mail Center. 	e application when submitting to the FDA at either the CBER or
1. COMPANY NAME AND ADDRESS (include name, street	2. CONTACT NAME
address, city state, country, and post office code)	Marilyn Konicky
	2.1 E-MAIL ADDRESS
CONVATEC	marilyn.konicky@bms.com
200 HEADQUARTERS PARK DRIVE	2.2 TELEPHONE NUMBER (include Area code)
SKILLMAN NJ 08558 US	908-904-2541
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	
136121983	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 908-904-2235
 TYPE OF PREMARKET APPLICATION (Select one of the follow descriptions at the following web site: http://www.fda.gov/dc/mdufma Select an application type: 	
[X] Premarket notification(510(k)); except for third party	3.1 Select one of the types below
[] 513(g) Request for Information	[X] Original Application
[] Biologics License Application (BLA)	Supplement Types:
Premarket Approval Application (PMA)	[] Efficacy (BLA)
1) Modular PMA	[] Panel Track (PMA, PMR, PDP)
Product Development Protocol (PDP)	() Real-Time (PMA, PMR, PDP)
[] Premarket Report (PMR)	[] 180-day (PMA, PMR, PDP)
[] Annual Fee for Periodic Reporting (APR)	
[] 30-Day Notice	· · · ·
4. ARE YOU A SMALL BUSINESS? (See the instructions for more i	
[] YES, I meet the small business criteria and have submitted the requalifying documents to FDA.	equired [X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF TH APPLICABLE EXCEPTION.	HE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE
[] This application is the first PMA submitted by a gualified small but	conditions of use for a pediatric population
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[] This application is the first PMA submitted by a qualified small bu- including any affiliates, parents, and partner firms [] This biologics application is submitted under section 351 of the Pu Health Service Act for a product licensed for further manufacturing us 6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FO PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION C subject to the fee that applies for an original premarket approval appl	conditions of use for a pediatric population [] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially DR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A DF USE FOR ANY ADULT POPULATION? (If so, the application is lication (PMA).)

ConvaTec, A Division of E.R. Squibb and Sons I.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118^{age 1 of 133}

Section 2 - CDRH Premarket Review Cover Sheet

Description	Page
CDRH Premarket Review Submission Cover Sheet FDA-3514 AQUACEL®	3
CDRH Premarket Review Submission Cover Sheet FDA-3514 AQUACEL® Ag	8

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CDRH PRE	DEPARTMENT OF HEALTH AN FOOD AND DRUG AD MARKET REVIEW S	MINISTRATION		SHEET	Expiration	roval 9010-0120 Date: August 31, 2010. Statement on page 5.
Date of Submission	User Fee Payment ID (b)(4)	Number		FDA	Submission Docume	ent Number (if known)
SECTION A PMA Original Submission Premarket Report Modular Submission Amendment Report Report Amendment Licensing Agreement IDE Originat Submission Amendment Supplement	PMA & HDE Supplement Regular (180 day) Special Panel Track (PMA Only) 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Amendment to PMA &HDE Supplement Other Humanitarian Device Exemption (HDE) Original Submission Amendment Supplement Report Report	TYPE OF S PDP Original PDP Notice of Cou Amendment	mpletion to PDP ion Petition nission	Crigina Crigina Spi Abli sec Additio Third P Evalua Class	510(k) I Submission: ditional ecial previated (Complete tion I, Page 5) nal Information earty tion of Automatic s III Designation (De Novo) I Submission nal Information	Meeting Pre-510(K) Meeting Pre-IDE Meeting Pre-PDA Meeting Day 100 Meeting Agreement Meeting Determination Meeting Other (specify): Other Submission S13(g) Other (describe submission):
Have you used or cited Sta SECTION B Company / Institution Name		Yes D	CANT OR S	PONSOR	omplete Section I, Pa	
ConvaTec Division Name (<i>if applicable</i>) division of E.R. Squibb & Street Address 200 Headquarters Park Dr	Sons, L.L.C.		(908)90	r (including an	,	
City Skillman	· · · · ·		State / Provi New Jersey		ZIP/Postal Code 08558	Country USA
Contact Name Marilyn Konicky	•			-	•	
Contact Title Associate Director, US and	d International Regulatory Affai	irs	Contact E-m marilyn.kor	ail Address nicky@bms.c	om	
SECTION C Company / Institution Name	APPLICATION CORRE	ESPONDENT (e.	g., consulta	ınt, if differ	ent from above)	
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PAGE 1 of 5 PAGES PSC Graphics: (301) 443-2454 EF

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February 8, 2008

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SECTION D1	REASON FOR APPLICATION - PMA, PDP, OR	HDE
 Withdrawal Additional or Expanded Indications Request for Extension Post-approval Study Protocol Request for Applicant Hold Request for Removal of Applicant Hold Request to Remove or Add Manufacturing Site 	Change in design, component, or specification: Software / Hardware Color Additive Material Specifications Other (specify below)	Location change: Manufacturer Sterilizer Packager
Process change: Manufacturing Sterilization Packaging Other (specify below) Response to FDA correspondence:	Labeling change: Indications Instructions Performance Shelf Life Trade Name Other (specify below)	Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment Change in Ownership Change in Correspondent Change of Applicant Address
Other Reason (specify):		
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SECTION D3	REASON FOR SUBMISSION - 510(k)	
New Device	Additional or Expanded Indications	Change in Technology
Other Reason (specify): NOTE: This is a bundled submission - see	also the Submission Cover Sheet for AQUACEL Ag	Hydrofiber Wound Dressing

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PAGE 2 of 5 PAGES

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Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

510(k) Premarket Notification

February 8, 2008

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SEC	TION I		UTILIZATION OF STANDARDS		
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AQUACEL® and AQUACEL® Ag

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Contact Name Marilyn Konicky Contact Title Associate Director, US and	l International Regulatory Affai	irs	Contact E-m marilyn.kor		s.com	,		
SECTION C Company / Institution Name	APPLICATION CORRE	ESPONDENT (e.	g., consulta	int, if diffe	erent from a	above)		
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FORM FDA 3514 (9/07)							PAGE 1 o	f 5 PAGES

PAGE 1 of 5 PAGES PSC Graphics: (301) 443-2454 EF

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Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

Withdrawal Additional or Expanded Indications Request for Extension Post-approval Study Protocol Request for Applicant Hold Request for Removal of Applicant Hold Request to Remove or Add Manufacturing Site	Change in design, component, or specification: Software / Hardware Color Additive Material	Location change: Manufacturer Sterilizer
	Specifications Other (specify below)	Packager
Process change: Manufacturing Sterilization Packaging Other (specify below)	Labeling change: Indications Instructions Performance Shelf Life Trade Name Other (specify below)	
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FO	RM FDA 3514 (9/07)		·									PAGE 3 of 5 PAGES
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ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification February 8, 2008 AQUACEL® and AQUACEL® Ag

FORM FDA 3514 (9/07)

Note: Submission of this information does not affect the need to submit a 2891 or 2891 a Device Establishment Registration form. FDA Document Number (<i>if known</i>) SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION Image: Section of this information does not affect the need to submit a 2891 or 2891 a Device Establishment Registration form. FDA Document Number (<i>if known</i>) SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION Image: Section of this information form. Manufacturer Contract Sterilizer Image: Section of the stablishment Identifier (FEI) Number Image: Stablishment Registration Number Contract Sterilizer Image: Section Name Establishment Registration Number Establishment Registration Number Stablishment Registration Number Image: Section Name (<i>if applicable</i>) Phone Number (<i>including area code</i>) Phone Number (<i>including area code</i>)	
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ConvaTec, A Division of E.R. Squibb and Sons L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement Standards No. Standards Standards Title Version Date Organization 1 Standards No. Standards Standards Title Version Date Organization 2 Standards Title Standards No. Standards Version Date Organization 3 Standards No. Standards Standards Title Version Date Organization 4 Standards No. Standards Standards Title Version Date Organization 5 Standards Standards No. Standards Title Version Date Organization 6 Standards No. Standards Standards Title Version Date Organization 7 Please include any additional standards to be cited on a separate page. Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

FORM FDA 3514 (9/07)

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200 Headquarters Park Drive Skillman, NJ 08558 908 904-2500

February 8, 2008

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

RE: 510(k) Premarket Notification - Traditional Bundled 510(k) AQUACEL[®]Hydrofiber[®] Wound Dressing AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Dear Sir/Madam: -

In accordance with Section 510(k) of the Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, subpart E, this Premarket Notification is being submitted in duplicate by ConvaTec, a Division of E.R. Squibb & Sons, L.L.C.

This is a "bundled 510(k)" for AQUACEL[®] Hydrofiber[®] Wound Dressing and for AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing. Under the FDA guidance document: *Guidance for Industry and FDA Staff Bundling Multiple Devices or Multiple Indications in a Single Submission, June 22, 2007*, we are submitting both premarket notifications in one 510(k) submission.

This bundled 510(k) seeks clearance for additional and clarified indications for AQUACEL[®] Hydrofiber[®] Wound Dressing previously cleared under K943258, K982116 and K063271 and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing previously cleared under K013814 and K063271. Claims to be used in advertising are contained in Section 13 of this application.

Both Hydrofiber[®] products are sterile devices currently marketed by ConvaTec as overthe-counter and prescription medical devices. The only difference between the Hydrofiber[®] dressings is the incorporation of 1.2% ionic silver in the AQUACEL[®] Ag dressings. No significant changes have been made to the Hydrofiber[®] dressings in components or composition and the previously cleared products marketed under AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing – they are the same dressing. ConvaTec has conducted a clinical performance study to provide support for the indication of "management of donor sites". The full study report is included in Section 20 of this application.

AQUACEL[®] Hydrofiber[®] Wound Dressing is classified under 21CFR 878.4018, classification name, *dressing, wound, hydrophilic*, product code is NAC and it is a Class I device. AQUACEL[®] Ag Hydrofiber[®] Silver Impregnated Antimicrobial Dressing has the classification name, *dressing, wound, drug*, product code is FRO and the device is unclassified.

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional and clarified indications and claims for these products. We consider this information to be confidential commercial information and, therefore, exempt from public disclosure.

The Establishment Registration for the manufacturing site at (b)(4)

The Owner/Operator number is: (b) 4)

Two copies of the 510(k) have been submitted in hard copy including the Premarket Review Submission Cover Sheet and a detailed Table of Contents.

Please see the Design and Use of the Device table attached to this letter for the submitted devices as outlined in the 510(k) format document dated August 12, 2005.

We trust you will find the enclosed satisfactory; however, should you have any questions, please contact me at (908)-904-2541 or by fax at (908)-904-2235 or via e-mail at marilyn.konicky@bms.com.

Sincerely.

Marilyn Konicky Associate Director US and International Regulatory Affairs

Attachment

MK/pk

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A	X	
Is the device intended for over-the-counter use (21 CFR 807 subpart C) ^A ?	X	
Does the device contain components derived from a tissue or other biologic source?		х
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		Х

^AA device may be intended for both prescription and over the counter use. If so, the answer to both of these questions is yes.

AQUACEL[®] Hydrofiber[®] is a registered trademark of E.R. Squibb & Sons, L.L.C. AQUACEL[®] Ag Hydrofiber[®] is a registered trademark of E.R. Squibb & Sons, L.L.C.

(b)(4) Draft Document

510(k) Precededstphotessade and en FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 AQUACEL and AQUACEL Ag February 8, 2008

SECTION 6: TRUTHFUL AND ACCURACY STATEMENT

As required by 21 CFR 807.87(k), I certify that, in my capacity as Associate Director, US and International Regulatory Affairs for ConvaTec, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



al Regulatory Affairs

February 8, 2008

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February 8, 2008

SECTION 7: CLASS III SUMMARY AND CERTIFICATION

Neither product, AQUACEL[®] Hydrofiber[®] Wound Dressing nor AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing, is a Class III Device.

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification Febr AQUACEL® and AQUACEL® Ag

SECTION 8: FINANCIAL CERTIFICATION STATEMENT

Please see attached Form FDA 3454.

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510(k)) Premarket	Notification
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AQUAGEL and AQUACEL Ager FOIA Request # 2015-8413 Released by CDRH 56 9208 2008

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396 Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please m	ark the applicable check	box.

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	(b)(6)			

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME (b)(6)		ITLE ice President, Global Medical Affairs
FIRM/ORGANIZATION		
ConvaTec, A Division of E	.R. Squibb & Sons, L.L.C.	
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nformation unless it displays collection of information is e nstructions, searching existin	or sponsor, and a person is not required to respon a currently valid OMB control number. Public rep stimated to average 1 hour per response, includin g data sources, gathering and maintaining the collection of information. Send comments regardin section of information to the address to the right:	porting burden for this ng time for reviewing necessary data, and Department of Health and Human Services Food and Drug Administration 5600 Fishers Lane, Room 14C-03

FORM FDA 3454 (4/06)

PSC Graphics: (301) 443-1090 EF

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Form FDA 3454 Financial Certification (Continued)

Study Name (b)(4) Study No.: (b)(4) (b)

Investigator List:

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SECTION 9: DECLARATION OF CONFORMITY AND SUMMARY REPORTS

To date, no performance standards or special controls have been issued by the Food and Drug Administration for this type of device.

As required under Section 514 of the Food, Drug and Cosmetic Act, these products, AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing, are manufactured in accordance with 21 CFR Part 820, Quality System Regulations.

There are no national or international standards referenced within this 510(k), therefore, Form FDA 3654 Standards Data Report for 510(k)s has not been included.

SECTION 10: EXECUTIVE SUMMARY

This bundled 510(k) seeks clearance for additional and clarified indications for both AQUACEL[®] Hydrofiber[®] Wound Dressing (K943258/K982116/K063271) and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing (K013814/K063271).

Description of Device

Both dressings are soft, sterile, non-woven pad or ribbon dressings composed of sodium carboxymethylcellulose. AQUACEL[®] Ag dressing also contains 1.2% ionic silver, which is included for microbial protection. The Hydrofiber[®] technology of the dressings produces a cohesive gel which provides a moist wound healing environment. There have been no significant changes to the components, composition, methods of sterilization or manufacture for either dressing

AQUACEL[®] Hydrofiber[®] Wound Dressing

This dressing is a soft, sterile, non-woven pad or ribbon dressing composed of hydrocolloid fibers (sodium carboxymethylcellulose) (Hydrofiber®). This highly absorbent and conformable dressing absorbs wound fluid and creates a soft gel, maintains a moist environment which supports the body's healing process and aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.

AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

AQUACEL® Ag Dressing has the same composition as AQUACEL® Dressing but also contains silver impregnated into the Hydrofiber® dressing. This dressing is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver, which allows for a maximum of 12mg of silver in a 4 inch by 4 inch dressing. The dressing absorbs high amounts of wound fluid and bacteria; creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement) without damaging newly formed tissue. The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

Indications for Use:

AQUACEL® Hydrofiber® Wound Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

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

 Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

- Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- Surgical wounds (post-operative, donor sites, dermatological)
- Partial thickness (second degree) burns
- Traumatic or surgical wounds left to heal by secondary intention such as dehisced surgical incisions¹

- Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹

- Traumatic wounds²
- Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Management of painful wounds

¹Clarified / New Indication, not previously included in this format under K943258, K982116, or K063271

²Indication re-positioned within Indications for Use statement

Indications for Use

AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

For Over-the-Counter use, AQUACEL® Ag Hydrofiber Dressing may be used for:

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

Under the supervision of a healthcare professional, AQUACEL® Ag Hydrofiber Dressing may be used for the management of infected wounds and wounds at risk of infection¹:

- Wounds as an effective barrier to bacterial penetration to 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 incisions¹
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthópedic and vascular)¹
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites¹
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds

AQUACEL® Ag may be used on minimally exuding, non-exuding and dry wounds, as stated in the **DIRECTIONS FOR USE**.

¹Clarified / New Indication, not previously included in this format under K013814 or K063271

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Device Comparison Tables

Tables of Similarities and Differences are provided on the following pages for both the proposed AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing compared to the respective predicates with the same trade-names (AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing).

510(k) F. Jrket Notification AQUACEL® and AQUACEL® Ag

AQUACEL[®] Hydrofiber[®] Wound Dressing Table of Similarities and Differences

ACUACEL (predicate) Juntarities K943258/K982116/K063271 Same dressing composition External Wound Dressing Same dressing composition There is no difference in the intended use - absorbs wounds and design. Same basic - provides a moist wound healing intended use (management of wound healing - provides a moist wound healing exudate, protection, wound - provides a moist wound healing management of pain, provision of moist wound	Descriptions Realing, transmistions AQUACH: ® Dressings are currently indicated for use on "surgical bent freerations Refut to heal by essentially the same or traumatic wounds, left to heal by secondary intent" and "ungical constant", and "ungical constant and "ungical constant and "ungical constant", and "ungical constant and "ungical constant and "ungical constant", and "ungical constant and "ungical constant", and "ungical constant and "ungical constant and "ungical constant and "ungical constant and "ungical constreation", and "ungical constreati "ungical constant "
ACOACEL (proposed) External Wound Dressing - absorbs wound exudate - protects wounds - management of painful wounds - provides a moist wound healing environment	 Over-the-Counter Use abrasions abrasions abrasions abrasions minor cuts minor cuts minor cuts minor scalds and burns Under the supervision of a Healthcare Professional, AQUACEL® may be used for the management of: leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers surgical wounds (post-operative, donor sites, dermatological) partial thickness (second degree) burns traumatic or surgical wounds that have been left to heal by secondary intention, such as dehisced surgical incisions¹ surgical wounds that heal by primary intent, such as dehisced surgical wounds that have been left to heal by secondary intentions, such as dehisced surgical incisions ¹ traumatic wounds² local management of wounds prone to bleeding such as wounds that have been medanically or surgically debrided and donor sites.

¹Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271 ²Indication re-positioned within Indications for Use statement

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Table of Similarities and Differences AQUACEL[®] Hydrofiber[®] Wound Dressing

Differences	No differences	No differences	The extended wear time of 14 days for donor sites is supported by clinical usage in this application. Clinical evidence to support this change is provided in Section 20, clinical study report (0)(4)	No differences	No Differences
Similarities	Same	Same	Same, with exception of changing frequency for donor sites.	Same	Same
AQUACEL [®] (predicate) K943258/K982116/K063271	The dressing absorbs wound fluid and creates a soft conformable get, 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.	Sterile Absorbs exudates or blood Forms a soft conformable gel	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For second degree burns, the AQUACEL® may be teft in place for up to 14 days provided there is no clinical evidence of infection.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.	When necessary, fully saturate dressing with sterile saline and allow to soak into the dressing. Appropriate supportive measures should be taken where indicated (e.g., compression bandaging for vênous leg ulcers or pressure relief measures for pressure ulcers). For fistulac and sinus tracts employ appropriate techniques during insertion and removal. In second degree burns consider alternate surgical procedures if the wound has not reepihelialized after fourteen days. The dressing is not intended for use as a surgical sponge.
AQUACEL [®] (proposed)	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 (autofytic debridement), without damaging newly formed tissue.	Sterile Absorbs exudates or blood Forms a soft conformable gel	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For partial thickness (second degree) burns, the AQUACEL [®] dressing may be left in place for up to 14 days or until clinically indicated. For donor sites, the AQUACEL [®] dressing may be left in place for up to 14 days.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.	When necessary, fully saturate dressing with sterile saline and allow to soak into the dressing. Appropriate supportive measures should be taken where indicated (e.g., compression bandaging for venous leg ulcers or pressure relief measures for pressure ulcers). For fistulate and sinus tracts employ appropriate techniques during insertion and removal. In second degree burns consider alternate surgical procedures if the wound has not reepithelialized after for use as a surgical sponge. The Precautions remain the same and unchanged from the predicate 510(k) K063271. For ease of review, the entire list of Precautions and Observations is included in the package from the predicate 510(k)
Parameter	Mode of Action	Characteristics	ley	ations	Precautions

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ConvaTcc, A Division of E.R. Squibb and Sons, L.L.C.

¹Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271 ²Indication re-positioned within Indications for Use statement

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Similarities and Differences AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

Differences	No Differences
Similarities	Same
AQUACEL [®] Ag (predicate) K013814/K063271	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment
AQUACEL [®] (predicate) K943258/K982116/K063271	 External Wound Dressing absorbs wound exudate protects wounds for the management of painful wounds provides a moist wound healing environment
AQUACEL [©] Ag (proposed)	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment
Parameter	Intended Use

⁴Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Febr..... 8, 2008

Table of Similarities and Differences AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

 AQUACEL® Ag (proposed) and both of the predicate dressings have essentially the same Indications for Use which include minor OTC wounds, difficult to heal chronic wounds (leg ulcers, pressure sores, etc), traumatic wounds, pressure sores, etc), traumatic wounds, wounds that have been left to heal by secondary intention. Similarly to the wounds that have been left to heal by secondary intention. AQUACEL® Ag (proposed) indications, the predicate wounds and surgical), se also has Indications, the predicate dressing also has Indications for Use which include other surgical wounds also has Indications for Use which heal by primary intent. AQUACEL® Ag (proposed) and both of the predicate dressings are of the same design and consist of Hydrofiber®. The AQUACEL® Ag (proposed) and same dressing and both contain silver (1.2%) in addition to the Hydrofiber® 			AUACEL ² (predicate) K943258/K982116/K063271	AQUACEL® Ag (predicate) K013814/K063271	Similarities	Differences
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vith exudate contain silver (1.2%) in nanagement of addition to the Bainful wounds Hydrofiber® component.		- management of painful wounds		- oncology wounds	same dressing and both	to support these indications for Hydrofiber®
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atinful wounds Hydroffber® component.				 management of 	addition to the	dressings.
			-	painful wounds	Hydrofiber®	1
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Febi , 8, 2008

AQUACEL[®] Ag Hydrofiber[®] Wound Dressing Table of Similarities and Differences

Parameter	AQUACEL ^{&} Ag (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	AQUACEL [®] Ag (predicate) K013814/K063271	Similarities	Differences
Components	Non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber®) and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch by 4 inch dressing.	Non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber®).	Non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber®) and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch by 4 inch dressing.	Both dressings are non- woven dressings composed of sodium carboxymethylcellulose (Hydrofiber®)	The only difference between the dressings is the incorporation of 1.2% ionic silver in the AQUACEL® Ag dressings. There is no difference in components between AQUACEL® Ag (proposed) and the previously cleared product marketed by the same name – AQUACEL® Ag (predicate) - they are the same dressing.
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 (auolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL @ Ag 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 uncecessary material from the wound (autolytic debridement) without damaging newly formed tissue.	The dressing absorbs wound fluid and creates a soft gel, which maintains a moist wound envist wound envist wound the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without debridement) without debridement without debrid	Same	The silver in the AQUACEL ® Ag dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. There is no difference in the mode of action between AQUACEL® Ag (proposed) and the previously cleared product marketed by the same name – AQUACEL® Ag (predicate) - they are the same dressing.
Characteristics	Sterile Absorbs exudates (including bacteria) or blood Forms a soft conformable gel Antimicrobial properties from ionic silver.	Sterile Absorbs exudates (including bacteria) or blood Forms a soft conformable gel	Sterile Absorbs exudates (including bacteria) or blood blood soft gel Antimicrobial properties from ionic silver.	Both dressings are sterile, absorb exudate (including bacteria) or blood and form a soft gel.	The antimicrobial properties of AQUACEL® Ag. There is no difference in the characteristics between AQUACEL® Ag (proposed) and the previously cleared product marketed by the same name – AQUACEL® Ag (predicate) - they are the same dressing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) I. Lirket Notification AQUACEL® and AQUACEL® Ag

February 8, 2008

Table of Similaritics and Differences AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

Parameter	AQUACEL [®] Ag (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	AQUACEL [®] Ag (predicate) K013814/K063271	Similarities	Differences	
	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For partial thickness (second degree) burns, the AQUACEL® Ag dressing may be left in place for up to 14 days or until clinically indicated. For donor sites, the AQUACEL® Ag dressing may be left in place for up to 14 days.	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For second degree burns, the AQUACEL® may be left in place for up to 14 days provided there is no clinical evidence of infection.	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For partial thickness (second degree) burns, the AOUACEL® Ag degree) burns, the AOUACEL® Ag dressing may be left in place for up to 14 days or until clinically indicated.	Same, with exception of changing frequency for donor sites.	The extended wear time of 14 days for donor sites is supported by clinical usage in this application. Clinical evidence to support this change is provided in Section 20, (b) (4)	
cations	Contraindications Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.	Same	No differences	

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¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

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Febru., y 8, 2008

able of Similaritie QUACEL [®] Ag H	Table of Similarities and Differences AQUACEL [®] Ag Hydrofiber [®] Wound Dressing				
Parameter	AQUACEL [®] Ag (proposed)	AQUACEL [©] (predicate) K943258/K982116/K063271	AQUACEL [®] Ag (predicate) K013814/K063271	Similarities	Differences
Precautions	When necessary, fully saturate dressing with sterile saline and allow to soak into the dressing. Appropriate supportive measures should be taken where indicated (e.g., compression bandaging for venous leg ulcers or pressure relief measures for pressure ulcers). For fistulae and sinus tracts employ appropriate techniques during insertion and removal. In second degree burns consider alternate surgical procedures if the wound has not recpithelialized after fourteen days. The dressing is not intended for use as a surgical sponge. The use of this dressing has not been studied in	When necessary, fully saturate dressing with sterile saline and allow to soak into the dressing. Appropriate supportive measures should be taken where indicated (e.g., compression bandaging for venous leg ulcers or pressure relief measures for pressure ulcers). For fistulae and sinus tracts employ appropriate techniques during insertion and removal. In second degree burns consider alternate surgical procedures if the wound has not recpithelialized after fourteen days. The dressing is not intended for use as a surgical sponge. The use of this dressing has not been studied in wounds due to herpes simplex	When necessary, fully saturate dressing with sterile saline and allow to soak into the dressing. Appropriate supportive measures should be taken where indicated (e.g., compression bandaging for venous leg ulcers or pressure relief measures for pressure ulcers). For fistulae and sinus tracts employ appropriate techniques during insertion and	Same	No differences
	monus and to netpes simplex of		degree burns consider		

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

dressing is not intended

reepithelialized after

wound has not

alternate surgical procedures if the fourteen days. The for use as a surgical this dressing has not been studied in wounds due to herpes simplex

or impetigo.

sponge. The use of

package insert which is located in Sections 13 and 20 of this submission

Observations is included in the entire list of Precautions and

The Precautions remain the same and unchanged from the predicate 510(k) K063271. For ease of review, the

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¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)	Summary of Performance Testing	

(b)(4)

SECTION 11: DEVICE DESCRIPTION

The descriptions of the devices are summarized below. The components and composition, for both products are unchanged from the information provided in the premarket notifications that are referenced in Section 4 of this submission.

Both dressings have over-the-counter indications for use such as abrasions and lacerations. Both dressings have indications for use under the supervision of a health care professional, including leg ulcers, pressure ulcers (Stages II-IV), diabetic ulcers, second degree burns, donor sites, surgical and traumatic wounds left to heal by secondary intent, management of painful wounds and for use on wounds prone to bleeding. AQUACEL[®] Ag Dressings are also indicated for exudate absorption in oncology wounds.

AQUACEL[®] Hydrofiber[®] Wound Dressing

This dressing is a soft, sterile, non-woven pad or ribbon dressing composed of hydrocolloid fibers (sodium carboxymethylcellulose). This conformable and highly absorbent dressing absorbs wound fluid and creates a soft gel which maintains a moist environment which supports the body's healing process and aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.

AQUACEL[®] Ag with Hydrofiber[®]

AQUACEL[®] Ag Dressing has the same composition as AQUACEL[®] Dressing but also contains silver impregnated into the dressing. This dressing is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver which allows for a maximum of 12mg of silver in a 4 inch by 4 inch dressing. The dressing absorbs high amounts of wound fluid and bacteria, and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement) without damaging newly formed tissue. A moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

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SECTION 12: SUBSTANTIAL EQUIVALENCE

AQUACEL® Hydrofiber® Wound Dressing

This is a bundled 510(k) submission for AQUACEL® Hydrofiber® Wound Dressing (AQUACEL®) and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (AQUACEL® Ag). The purpose of this 510(k) is to clarify the package inserts and, in particular, to clarify the Indications for Use, by inclusion of the following additional text:

Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

- Traumatic or surgical wounds left to heal by secondary intention, such as dehisced surgical incisions¹

- Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹

- Traumatic wounds²

AQUACEL® is substantially equivalent to previously cleared versions of AQUACEL® Hydrofiber® Dressing (listed below), without the addition of the above newly proposed indications and claims:

K063271 - bundled 510(k), included AQUACEL® and AQUACEL® Ag Dressings K982116 - AQUACEL® Hydrofiber Wound Dressing

K943258 - originally filed as ConvaTec Hydrocolloid Wound Dressing

Tables of Similarities and Differences are provided on following pages for both AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing. Following the tables, the clearance letters for the premarket notifications for AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing are enclosed.

¹Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271 ²Indication re-positioned within Indications for Use statement

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SECTION 12: SUBSTANTIAL EQUIVALENCE

AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

This is a bundled 510(k) submission for AQUACEL® Hydrofiber® Wound Dressing (AQUACEL®) and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (AQUACEL® Ag). The purpose of this 510(k) is to clarify the package inserts and, in particular, to clarify the Indications for Use by including the following additional text:

Under the supervision of a healthcare professional, AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing may be used for the management of infected wounds and wounds at risk of infection¹:

- Surgical wounds left to heal by secondary intention, such as dehisced surgical incisions¹;
- Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided **and donor sites**¹

AQUACEL® Ag is substantially equivalent to previously cleared versions of AQUACEL® Hydrofiber® Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing(listed below), without the addition of the newly proposed indications and claims:

K063271 - bundled 510(k), included AQUACEL® and AQUACEL® Ag Dressings K013814 - Absorbent Antimicrobial Wound Dressing (now marketed as AQUACEL Ag) K982116 - AQUACEL® Hydrofiber Wound Dressing

K943258 - originally filed as ConvaTec Hydrocolloid Wound Dressing



Tables of Similarities and Differences are provided on the following pages for both AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing. Following the tables, the clearance letters for the premarket notifications for AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing are enclosed.

¹Clarified / New Indication, not previously included in this format under K943258, K982116. K013814 or K063271

510(k) 1 urket Notification AQUACEL® and AQUACEL® Ag

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Table of Similarities and Differences AQUACEL [®] Hydrofiber [®] Wound Dr	Table of Similarities and Differences AQUACEL [®] Hydrofiber [®] Wound Dressing
raneter	AQUACEL [*] (proposed)
Intended Use	External Wound Dressing
	 absorbs wound exudate
	 protects wounds
	 management of painful wounds
	 provides a moist wound healing
	environment
T	

Differences	There is no difference in the intended use.		-	AQUACEL® Dressings are currently indicated for use on "surgical	or traumatic wounds left to heal by secondary intent" and .	dermatological)." The difference is intended to further clarify and	define these already cleared indications by amending the text to	include, "such as dehiseed surgical incisions" under those healing by secondary intent and "surgical wounds that heal by primary	intent, such as dermatological and surgical incisions (e.g.,	orthopedic and vascular)."		I us is supported by the Hydrotiber® technology in AQUACEL® dressing forming a soft gel which conforms to the mound motaxis	the wound from frictional forces, is highly absorbent, provides a	moist wound healing environment and aids in the management of	painful wounds. The Hydrofiber® technology in AQUACEL® also	alds in removing dead necrotic material from the wound without	usinging newly journed ussue. Currical succes (ustaired classwicce in this application) support the lise of the Hydrofiber® technology in	AOUACEL® Dressings for the management of surpical wounds and	incisions healed with primary intention.	-	The indication for use in traumatic wounds has been relocated to a	single separate bullet as opposed to the previous placement in two	separate sections – this is interface to simplify and clarify the Indications for Lise statement					No differences		
Similarities		intended use (management of wounds by absorption of	exutate, protection, management of pain, provision of moist wound		essentially the same	oposed	-	clarification and definition of the indications.							-													Same		
AQUACEL [©] (predicate) K943258/K982116/K063271	External Wound Dressing - absorbs wound exudate	 protects wounds management of painful wounds mrovides a motet wound healing 	environment	Over-the-Counter Use	- abrasions	- minor cuts	- minor scalds and burns	Under Supervision of a Healthcare	Professional, AQUACEL® may be used for	the management of:	 leg ulcers, pressure ulcers (Stage II- III) and distant antenna 	IV) and diabenc uicers - surgical wounds (nost-onerative donor	sites, dermatological)	- partial thickness (second degree) burns	- management of surgical or traumatic	wounds that have occurted to near by secondary intention	 local management of wounds that are 	prone to bleeding such as wounds that	have been mechanically or surgically	debrided, donor sites and traumatic	wounds	 management of painful wounds 						Non-woven sodium carboxy-	methylcellulose.	
AQUACEL [®] (proposed)	External Wound Dressing - absorbs wound exudate	 protects wounds management of painful wounds movides a moist wound healing 	environment	Over-the-Counter Use	- abrasions	- minor cuts	- minor scalds and burns	Under the supervision of a Healthcare	Professional, AQUACEL® may be used for	the management of:	- leg ulcers, pressure ulcers (Stage Il-	IV) and diagene uncers	donor sites, dermatological)	 partial thickness (second degree) 	burns	 naumane or surgical woulds that have been left to heal by secondary 	intention. such as dehisced surgical	incisions ¹	 surgical wounds that heal by 	primary intent, such as	dermatological and surgical	incisions (e.g. orthopedic and	- traumatic wounds ²	 local management of wounds prone to 	bleeding such as wounds that have	been mechanically or surgically	 debrided and donor sites management of painful wounds 	Non-woven sodium carboxy-	methylcellulose.	
Parameter	Intended Use			Indications for Use					•	-						-				·								Components		81

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¹Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271 ²Indication re-positioned within Indications for Use Statement ConvaTcc, A Division of E.R. Squibb and Sons, L.L.C.

510(k) , arket Notification AQUACEL® and AQUACEL® Ag

Table of Similarities and Differences ® Ę

Differences	No differences		-			No differences				clinical usage in this application.	Clinical evidence to support this change is provided in Section 20.					No differences	•		No Differences			•														
Similarities	Same					Same			Same, with exception of	changing trequency for donor sites						Same			Same					,												
AQUACEL* (predicate) K943258/K982116/K063271	The dressing absorbs wound fluid and creates a soft conformable pel, which	maintains a moist wound environment to	support the healing process. The dressing	aids in the removal of unnecessary material	Irom the wound (autolytic debridement), without damaging newly formed tissue	Sterile	Absorbs exudates or blood	Forms a soft conformable gel	Dressing may be left in place for up to 7	days, the dressing may require more frequent changes when used on heavily	exuating wounds For second degree	burns, the AQUACEL® may be left in place		clinical evidence of infection.		Do not use on patients who are sensitive to	or who have had allergic reactions to the	dressing or its components.	When necessary, fully saturate dressing with	descript Americani diluw to soak into une	utessing. Appropriate supportive incasures should be taken where indicated fe o	compression handaging for venous leg	ulcers or pressure relief measures for	pressure ulcers).	For fistulae and sinus tracts employ		removal. In second degree burns consider	anernare surgical procedures it the would has not reepithelialized after fourteen days.	The dressing is not intended for use as a	surgical sponge.						
AUAUEU- (proposed)	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	Irom the wound (autolytic debridement), without damaging newly formed tissue.	Sterile	Absorbs exudates or blood	Forms a soft conformable gel	Dressing may be left in place for up to 7	days; the dressing may require more frequent changes when used on heavily	exudating wounds. For nartial thickness	(second degree) burns, the AOUACEL®	dressing may be left in place for up to 14	days or until clinically indicated. For donor	I sites, the AUAUELT dressing may be left in place for up to 14 days.	Do not use on patients who are sensitive to	or who have had allergic reactions to the	dressing or its components.	When necessary, fully saturate dressing with	Associate Associate and a to solar field the	should be taken where indicated (e.o.	compression handaging for venous leg	ulcers or pressure relief measures for	pressure ulcers). For fistulae and sinus	tracts employ appropriate techniques during	insertion and removal. In second degree	burns consider alternate surgical procedures	fourteen days. The dressing is not intended	for use as a surgical sponge.		I be Precautions remain the same and unchanged from the predicate \$100k)	K063271. For ease of review, the entire list	of Precautions and Obscrvations is included	in the package insert which is located in	Sections 13 and 20 of this submission,	
	Mode of Action					Characteristics,			Changing Frequency							Contraindications			Precautions													-				·81

¹Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271 ²Indication re-positioned within Indications for Use Statement

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510(k) , arket Notification AQUACEL® and AQUACEL® Ag

Table of Similaritics and Differences

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AQU	'ACEL [®] Ag H _J	AQUACEL® Ag Hydrofiber® Wound Dressing				•
_	Parameter	AQUACEL [®] Ag (proposed)	AQUACEL [®] (predicate)	AQUACEL [®] Ag	Similarities	Differences
			K943258/K982116/K063271	(predicate)		
				K013814/K063271		
	Intended Usc	External Wound Dressing	External Wound Dressing	External Wound	Same	No Differences
-		 absorbs wound exudate 	 absorbs wound exudate 	Dressing		
_		 protects wounds 	 protects wounds 	 absorbs wound 		
_	,	 for the management of 	 for the management of painful 	exudate		
_		painful wounds	wounds	 protects wounds 		
•		 provides a moist wound 	 provides a moist wound healing 	 for the management 		
		heating environment	environment	of painful wounds		
				 provides a moist 		•
-	-			wound healing		
	-			environment		

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510(k) F. Jarket Notification AQUACEL® and AQUACEL® Ag

Differences	AQUACEL® Ag (proposed) is indicated for use		wounds at risk of infection. This wording has	been included to clarify that the 1.2% ionic	silver included in the dressing provides an	antimicrobial barrier that may be helpful, as part	of a protocol of care, in managing these wounds.		The Indications for Use of AQUACEL® Ag	(proposed) includes the addition of "such as	dehisced surgical wounds" to provide	clarification and better definition of the already	indicated surgical wounds healing by secondary	intention. These are typical of the surgical	wounds healing by secondary intent for which	AQUACEL® Ag is utilized.		The indications for Use of AQUACEL® Ag	(proposed) includes "surgical wounds that heal	by primary intent such as dermatological and	surgical incisions (c.g., orthopedic and	vascular)" and "donor sites". These indications	are not included in the predicate AQUACEL®	Ag instructions. The predicate AQUACEL®	Dressing, however, already has indications for	Use in "surgical wounds (post-operative, donor	sites, dermatological)".		AQUACEL® Ag (proposed) and both	predicates consist of Hydrofiber® technology.	AQUACEL® Ag only differs from	AQUACEL® in having silver (1.2%) in	addition to the Hydrofiber®. It is the	Hydrofiber® technology that provides the	performance characteristics that make	AQUACEL® (and also AQUACEL Ag)	suitable for use as a primary dressing in the	management of surgical wounds that heal by	primary and secondary intent, and donor sites.	Clinical evidence is included in this application	to support these indications for Hydrofiber®	(AQUACEL® and AQUACEL® Ag) dressings.	,			-
Similarities	AQUACEL® Ag	(proposed) and boin of	the predicate dressings	have essentially the	same Indications for	Use which include	minor OTC wounds,	difficult to heal chronic	wounds (leg ulcers,	pressure sores, etc),	traumatic wounds,	mechanically or	surgically debrided	wounds and surgical	wounds that have been	left to heal by	secondary intention.	Similarly to the	AQUACEL® Ag	(proposed) indications,	the predicate	AQUACEL® Dressing	also has Indications for	Use which include	other surgical wounds	(post-operative, donor	sites, dermatological),	some of which heal by	primary intent.		AQUACEL® Ag	(proposed) and both of	the predicate dressings	are of the same design	and consist of	Hydrofiber [®] . The	AQUACEL® Ag	(proposed) and	AQUACE®L Ag	(predicate) are the	same dressing and both	contain silver (1.2%) in	addition to the	Hydrofiber®	component.	
AQUACEL [®] Ag (predicate) K013814/K063271	Over-the-Counter Use		- lacerations	- minor cuts	- minor scalds	and burns		Under the supervision	of a Health Care	Professional,	AOUACEL [®] Ag mav	be used for the	management of:	 wounds as an 	effective barrier to	bacterial '	penetration to help	reduce infection	 partial thickness 	(second degree)	purns	 diabetic foot ulcers. 	leg ulcers, (venous	stasis ulcers,	arterial ulcers and	leg ulcers of mixed	etiology) and	pressure ulcers/sore	(partial & full	thickness)	 surgical wounds 	left to heal by	secondary intent	 traumatic wounds 	 wounds that are 	prone to bleeding,	such as wounds that	have been	mechanically or	surgically debrided	 oncology wounds 	with exudate	 management of 	painful wounds		
AQUACEL [©] (predicate) K943258/K982116/K063271	Over-the-Counter Use	- aDrasions	- lacerations	- minor cuts	 minor scalds and burns 	Under the supervision of a Healthcare	Professional, AQUACEL [®] may be used	for the management of:	-leg ulcers, pressure ulcers (Stage II-IV)	and diabetic ulcers	 surgical wounds (post-operative. 	donor sites, dermatological)	 partial thickness (second degree) 	pums	 management of surgical or traumatic 	wounds that have been left to heal by	secondary intention	 local management of wounds that are 	prone to bleeding, such as wounds	that have been mechanically or	surgically debrided, donor sites and	traumatic wounds	 the management of painful wounds 													-										
AQUACEL [®] Ag (proposed)	Over-the-Counter Use	- addrasions	- lacerations	- minor cuts	 minor scalds and burns 	Under the supervision of a Health	Care Professional, AQUACEL [®] Ag	may be used for the management of	infected wounds and wounds at	risk of infection ¹ :	 wounds as an effective barrier to 	bacterial penetration to 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 of	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 					
Parameter	Indications for	USC			•																-		٤																	-						
uestio	ons	?	C	on	Ita	act	, F	D	A/	'C	DI	Rŀ			E,	/D	ID	a	t C		۶R	:H	-F	0	IS	T/	٩T	Ū	S	@1	fda	a.ł	٦h	s.	gc	οv	or	r 3	30 ⁻	1-	79	6-	-81		۔ چ	

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¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

Februarý 8, 2008

Table of Similarities and Differences	AQUACEL [®] Ag Hydrofiber [®] Wound Dressing
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	AQUACEL ^T Ag (proposed)	AQUACEL ⁻ (predicate) K943258/K982116/K063271	AQUACEL [*] Ag (predicate) K013814/K063271	Similarities	Differences
_	Non-woven dressing composed of	Non-woven dressing composed of	Non-woven dressing	Both dressings are non-	The only difference between the dressings is the
	sodium carboxymethylcellulose	sodium carboxymethylceliulose	composed of sodium	woven dressings	incorporation of 1.2% ionic silver in the
_	(Hydrofiher®) and 1.2% ionic silver	(Hydroffiber®).	carboxymethylcellulose	composed of sodium	AQUACEL® Ag dressings. There is no
_	which allows for a maximum of 12mg		(Hydrofiber®) and	carboxymethylcellulose	difference in components between
	of silver for a 4 inch by 4 inch		1.2% ionic silver which	(Hydrofiber®)	AQUACEL® Ag (proposed) and the previously
	dressing.		allows for a maximum		cleared product marketed by the same name –
		-	of 12mg of silver for a		AQUACEL® Ag (predicate) - they are the same
			4 inch by 4 inch		dressing.
ľ	The dressing absorbs wound fluid and	The dressing absorbs wound fluid and	The dressing absorbs	Same	The silver in the AOIIACEL @ An drossing
	creates a soft conformable real which	creates a soft conformable real which	wound fluid and		kills wound harteria held in the dressing and
	maintains a moist wound environment	maintains a moist wound environment to	creates a soft cel		movides an antimicrohial harrier to protect the
	to sumort the healing process. The	support the healing process The	which maintains a		wound hed There is no difference in the mode
	dressing aids in the removal of	dressing aids in the removal of	tnoist wound		of action between AOUACEL® Ag (pronosed)
	unnecessary material from the wound	unnecessary material from the wound	environment to support		and the previously cleared product marketed by
<u> </u>	autolytic debridement) without	(autolytic debridement) without	the healing process		the same name – AOIIACET (® Ao (nuclicate) -
	damaging newly formed riscue. The	damaoing newly formed tissue	The dressing aids in the		they are the same dressing
	silver in the AOI IACFL ® A o		ressonant jo lavoran		
,	dressing kills wound hacteria held in		material from the		
	the dressing and provides an		wound (autolytic		-
	antimicrobial barrier to protect the		debridement) without		
	wound bed		damaging newly		
			formed tissue. The		
			silver in the	•	
	,		AQUACEL ® Ag		-
			dressing kills wound		
			bacteria held in the	3	
			dressing and provides		
			to protect the wound		
			bed.		
•1	Sterile A transfer (and und in a trated)	Sterile	Sterile	Both dressings are	The antimicrobial properties of AQUACEL®
•	AUSOLUS EXULUAIES (INCLUDING DACIENA)	Absorbs exudates (including pacteria)	Absulus cyudaics	SICILIC, AUSOLU CAUDAIC	
<u> </u>	or blood		(including bacteria) or	(including bacteria) or	between AQUACEL® Ag (proposed) and the
_	Forms a soft conformable get	Forms a sort conformable gel	Doold	DIOOD AND IOTTI A SOIL	previously cleared product marketed by the
1	Antimicrobial properties from jonic		Forms a soft gel	gel.	same name – AQUACEL® Ag (predicate) -
	SIIVEL.			-	urey are une sainte uressing.
		-	3//VC1.	_	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81

Page 54 of 133

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C.

¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

Feb. , 8, 2008

510(k) 1 ¹rket Notification AQUACEL® and AQUACEL® Ag

Differences	The extended wear time of 14 days for donor sites is supported by clinical usage in this application. Clinical evidence to support this change is provided in Section 20, (b)(4) (b)(4) Lesting	No differences
Similarities	Same, with exception of changing frequency for donor sites.	Same
AQUACEL® Ag (predicate) K013814/K063271	Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds. For partial thickness (second degree) burns, the AQUACEL® Ag dressing may be left in dressing may be left in place for up to 14 days or until clinically indicated.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.
AQUACEL® (predicate) K943258/K982116/K063271	Dressing may be left in place for up to 7 days, the dressing may require more frequent changes when used on heavily studating wounds. For second degree burns, the AQUACBL® may be left in place for up to 14 days provided there is no clinical evidence of infection.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.
AQUACEL [®] Ag (proposed)	Dressing may be left in place for up to ' 7 days; the dressing may require more frequent changes when used on heavity exudating wounds. For partial thickness (second degree) burns, the AQUACEL® Ag dressing may be left in place for up to 14 days or until clinically indicated. For donor sites, the AQUACEL® Ag dressing may be left in place for up to 14 days.	Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components.
Parameter	Changing Frequency	Contraindications

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271 ConvaTcc, A Division of E.R. Squibb and Sons, L.L.C.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81

Febr..... 8, 2008

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Parameter	AQUACEL [*] Ag (proposed)	AQUACEL [®] (predicate) K943258/K982116/K063271	. AQUACEL [®] Ag (predicate) K013814/K063271	Similarities	Differences	
Precautions	When necessary, fully saturate	When necessary, fully saturate dressing	When necessary, fully	Same	No differences	
	dressing with sterile saline and allow	with sterile saline and allow to soak into	saturate dressing with			
	to soak into the dressing. Appropriate	the dressing. Appropriate supportive	sterile saline and allow			
	supportive measures should be taken	measures should be taken where	to soak into the			
	where indicated (e.g., compression	indicated (e.g., compression bandaging	dressing. Appropriate			
	bandaging for venous leg ulcers or	for venous leg ulcers or pressure relief	supportive measures			
	pressure relief measures for pressure	measures for pressure ulcers). For	should be taken where			
	ulcers). For fistulae and sinus tracts	fistulae and sinus tracts employ	indicated (e.g.,			
	employ appropriate techniques during	appropriate techniques during insertion	compression bandaging			
	insertion and removal. In second	and removal. In second degree burns	for venous leg ulcers or			
	degree burns consider alternate	consider alternate surgical procedures if	pressure relief			
	surgical procedures if the wound has	the wound has not reepithelialized after	measures for pressure			
	not reepithelialized after fourteen	fourteen days. The dressing is not	ulcers). For fistulae		,	
	days. The dressing is not intended for	intended for use as a surgical sponge.	and sinus tracts employ			
	use as a surgical sponge. The use of	The use of this dressing has not been	appropriate techniques			
	this dressing has not been studied in	studied in wounds due to herpes simplex	during insertion and			
	wounds due to herpes simplex or	or impetigo.	removal .In second			
	impetigo.		degree burns consider			
			alternate surgical			
	The Precautions remain the same and		procedures if the			
,	unchanged from the predicate 510(k)		wound has not			
	K063271. For ease of review, the		rcepithelialized after			
	entire list of Precautions and		fourteen days. The			
	Observations is included in the		dressing is not intended			
	package insert which is located in		for use as a surgical			
	Sections 13 and 20 of this submission		sponge. The use of			
		-	this dressing has not			
			been studied in wounds	,		
			due to herpes simplex			
			au immetica			

¹Clarified / New Indication, not previously included in this format under K943258, K982116, K013814 or K063271

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C.

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510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

February 8, 2008



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

ConvaTec % Ms. Marilyn Konicky Associate Director, Regulatory Affairs 200 Headquarters Park Drive Skillman, New Jersey 08558

APR 16 2007

Re: K063271

Trade/Device Name: AQUACEL[®] Hydrofiber[®] Wound Dressing AQUACEL[®] Ag with Hydrofiber[®]

Regulatory Class: Unclassified Product Code: FRO Dated: April 5, 2007 Received: April 10, 2007

APR 2 5 200 Regulatory Affairs

Dear Ms. Konicky:

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 such 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); 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.

February 8, 2008

Page 2 – Ms. Marilyn Konicky

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <u>http://www.fda.gov/cdrh/industry/support/index.html</u>.

Sincerely yours, Mark N. Melkerson

Director Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification Feb AQUACEL® and AQUACEL® Ag

February 8, 2008



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Demetrios Kydonieus Director, Regulatory Affairs ConvaTec 200 Headquarters Park Drive Skillman, NJ 08558

Re: K013814

Trade/Device Name: Absorbent Antimicrobial Wound Dressing Regulatory Class: Unclassified Product Code: FRO Dated: April 15, 2002 Received: April 16, 2002

Dear Mr. Kydonieus:

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.

JUN 21 2002

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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February 8, 2008

Page 2 – Mr. Demetrios Kydonieus

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D. Director Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

February 8, 2008



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

SEP 8 1998

Mr. Ameer Ally Director, Regulatory Affairs ConvaTec 100 Headquarters Park Drive Skillman, New Jersey 08558

Re: K982116

Trade Name: Aquacel Hydrofiber Wound Dressing Regulatory Class: Unclassified Product Code: KMF Dated: May 28, 1998 Received: June 16, 1998

Dear Mr. Ally

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

- 2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
- 3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
- 4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

February 8, 2008

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Page 2 - Mr. Ameer Ally

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
 Director
 Division of General and
 Restorative Devices
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

Enclosure

ConvaTec, A Division of E.R. Squibh and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification February 8, 2008 AQUACEL® and AQUACEL® Ag

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service Food and Drug Administration AUG 1994 1390 Piccard Drive Rockville MD 20850 Ms. Karen Horgan · Associate Director, Regulatory Affairs Convatec Division of Bristol-Myers Squibb Company P.O. Box 5254 Princeton, New Jersey 08543-5254 763 G Re: K943258 ConvaTec Hyrocolloid Wound Dressing Regulatory Class: Unclassified ងរ Product Code: KMF Dated: July 1, 1994 Received: "July:6; =1994 Dear Ms. Horgan: We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). You may therefore, market the device, subject to the general controls provisions of the Act and the following limitations: This device may not be labeled for use on third 1. degree burns. This device may not be labeled as having any 2. accelerating effect on the rate of wound healing or epithelization. This device may not be labeled as a long-term, 3. permanent, or no-change dressing, or as an artificial (synthetic) skin. This device may not be labeled as a treatment or a 4. cure for any type of wound. The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

> 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.

ConvaTec, A Division of E.R. Squibb and Sons, L.L. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification Feb AQUACEL® and AQUACEL® Ag

February 8, 2008

Page 2 - Ms. Karen Horgan

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D. Director Division of General and Restorative Devices Office of Device Evaluation Center for Devices and Radiological Health

February 8, 2008

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SECTION 13: PROPOSED LABELING

Packaging Components

The individual dressing package and the cartons are unchanged from the previous premarket notification for these products, therefore, they are not being resubmitted at this time.

Package Inserts

Draft package inserts follow for each of the products. The drafts contain the revised Indications for Use sections for each product. Supporting documentation for the additional/clarified indications is included in Section 20 of this submission. The current package inserts are also included and follow the draft package inserts.

Advertising and Promotion

The additional statements to be used in the advertising and promotion of both products are listed below.

AQUACEL[®] and AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

- The gelling properties of Hydrofiber[®] technology protects the incision site and provides for non-traumatic removal of the dressing.
- Absorbs and wicks away drainage.
- Soft and conformable to the incision site.

AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

- In *in vitro* studies on surgical incisions, silver prevents colonization in the dressing and acts to kill micro-organisms, including MRSA and VRE which can cause infection.
- Provides an antimicrobial barrier to the incision site.

ConvaTec, A Division of EB South and Sons HJOCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81 18 contact FDA/CDRH/OCE/DID at CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81 18 contact FDA/CDRH/OCE/DID at CDRH/OCE/DID at

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(b)

SECTION 14: STERILIZATION AND SHELF LIFE

Sterilization

The information for the sterilization of both AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing is unchanged from the information and data submitted in the original and subsequent 510(k)s.

Shelf Life

The information for the shelf life of both AQUACEL® Hydrofiber® Wound Dressing and AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing is unchanged from the information and data submitted in the original and subsequent 510(k)s.

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SECTION 15: BIOCOMPATIBILITY

Biocompatibility testing in accordance with ISO 10993 has been performed for both products covered under this bundled 510(k). (b)(4)



Biocompatibility tests were conducted on both dressings in compliance with ISO 10993 and US Good Laboratory Practices (GLP) regulations.

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification AQUACEL® and AQUACEL® Ag

February 8, 2008

SECTION 16: SOFTWARE

This is not applicable as the device is a wound dressing and contains no software.

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 WS

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SECTION 17: ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This is not applicable as the device is a wound dressing and has no electromagnetic or electrical components.

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification February 8, 2008 AQUACEL® and AQUACEL® Ag

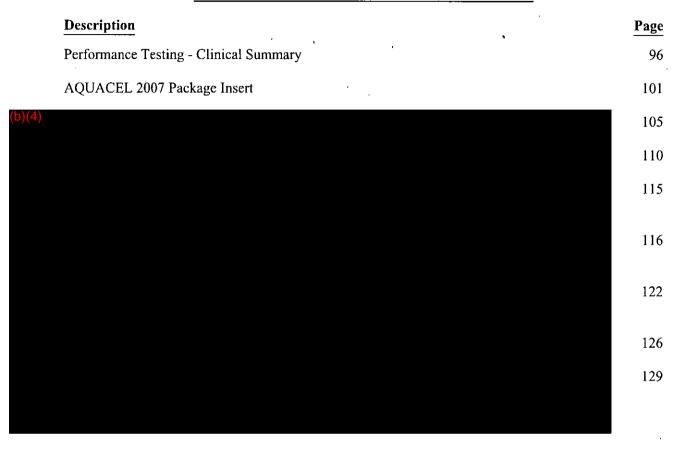
SECTION 18: PERFORMANCE DATA – BENCH

Performance data has been submitted for both products covered under this bundled								
<u>510(k)</u> . (b)(4)								
(b	- 4	1						
(b)(4)								

ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 2005

No animal performance data has been generated for this product to support the claim being sought in this 510(k).

Section 20 - Performance Testing - Clinical



ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796 บยา

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(h)(4)

SECTION 20: FERFORMANCE TESTING - CLINICAL								
(b)(4)								

SECTION 20: PERFORMANCE TESTING - CLINICAL

Current Package Insert

STERILE



INSTRUCTIONS FOR USE





Do Not Reuse

misc 2026

misc 2017

STERILE R

Gamma Sterilized



Order Number



Attention: See Instructions for Use

LOT

MISC 2063

Expiration Date

Lot

MISC 2060

PRODUCT DESCRIPTION

ConvaTec's AQUACEL® Hydrofiber® Wound Dressing is a soft, sterile, non-woven pad or ribbon dressing composed of hydrocolloid fibers (sodium carboxymethylcellulose.) This conformable and highly absorbent dressing absorbs wound fluid and creates a soft gel which maintains a moist environment which supports the body's healing process and aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.

This primary dressing should be used with a secondary cover dressing.

INDICATIONS

For Over - the - Counter use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

- abrasions
- lacerations
- minor cuts
- minor scalds and bums

ConvaTec, A Division of F.R. Squibb and Sons, L.L.C. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

- leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- surgical wounds (post-operative, donor sites, dermatological)
- second degree burns

AQUACEL® Hydrofiber® Wound Dressing may also be used for:

- management of surgical or traumatic wounds that have been left to heal by secondary intention.

- local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds.
- the management of painful wounds.

CONTRAINDICATIONS

AQUACEL® Hydrofiber® Wound Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

PRECAUTIONS AND OBSERVATIONS

- Should you observe irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation) or sensitivity (allergic reaction), consult a healthcare professional.
- If you have difficulty removing the dressing, the dressing should be fully saturated with sterile saline and allowed to soak into the dressing.
- Because AQUACEL® Hydrofiber® Wound Dressing provides a moist environment that supports the growth of new blood vessels, occasionally the delicate newly formed blood vessels may produce a blood stained wound fluid.
- The dressing may be used on infected wounds only under the care of a healthcare professional.
- This wound dressing should not be used with other wound care products without first consulting a healthcare professional.

In addition, for leg ulcers, pressure ulcers, diabetic ulcers, second degree burns, surgical or traumatic wounds left to heal by secondary intention:

- Treatment of wounds listed above should be under the supervision of a healthcare professional.
- Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers).
- Colonization of chronic wounds is common and is not a contraindication to the use of the dressing. The dressing may be used on infected wounds under medical supervision together with appropriate therapy and frequent monitoring of the wound.
- The control of blood glucose, as well as appropriate supportive measures, should be provided with diabetic foot ulcers.
- In cavity wounds, the ribbon dressing may be used to pack the wound. For wounds such as fistulae and sinus tracts, employ appropriate techniques during the insertion and removal of the dressing.
- In second degree burns, consider alternate surgical procedures if the wound has not reepithelialized after 14 days.
- AQUACEL® Hydrofiber® Wound Dressing is not intended for use as a surgical sponge.
- The use of AQUACEL® Hydrofiber® Wound Dressings has not been studied in wounds due to herpes simplex or impetigo.

DIRECTIONS FOR USE

- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- Apply the dressing to the wound and cover with a moisture retentive dressing (i.e., DuoDERM® Extra Thin, DuoDERM® CGF®, DuoDERM® CGF® Border Dressing), foam dressing, gauze, or other appropriate dressing. See individual package inserts for complete instructions for use. AQUACEL® Hydrofiber® Wound Dressing should overlap 1 cm or ½ inch onto the skin surrounding the wound.

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• When using AQUACEL® Hydrofiber® ribbon in deep cavity wounds, leave at least 2.5 cm or 1 inch outside the wound for easy retrieval. Only pack deep wounds to 80%, as AQUACEL® Hydrofiber® ribbon will expand to fill the wound space on contact with wound fluid.

- All wounds should be inspected frequently. Remove the AQUACEL® Hydrofiber® Wound Dressing when clinically indicated (i.e., leakage, excessive bleeding, suspicion of infection).
- The AQUACEL® Hydrofiber® Wound Dressing is designed to remain in place for a maximum of seven days. The dressing should be changed when it is saturated with wound fluid or if the cover dressing is leaking or the cover dressing's edges are bunching or rolling up.

FOR SECOND DEGREE BURNS:

- The AQUACEL® Hydrofiber® Wound Dressing should overlap 5 cm or 2 inches onto the skin surrounding the burn or other adjacent AQUACEL® Hydrofiber® Wound Dressing.
- The AQUACEL® Hydrofiber® Wound Dressing should be covered with sterile gauze and secured with medical tape.
- Remove the gauze cover dressing periodically and inspect the AQUACEL® Hydrofiber® Wound Dressing while it is still in place on the burn.
- Remove the AQUACEL® Hydrofiber® Wound Dressing when clinically indicated (e.g., leakage, excessive bleeding, clinical signs of infection). For second degree burns, the AQUACEL® Hydrofiber® Wound Dressing may be left in place for up to 14 days provided there is no clinical evidence of infection. As the burn wound reepithelializes, the AQUACEL® Hydrofiber® Wound Dressing will detach or be easily removed.
- This product is for single use only and is supplied sterile.
- Discard any unused portion of the product after dressing the wound.
- If the immediate product packaging is damaged, do not use.
- Store in a cool, dry place.

If further information or guidance is needed, please contact ConvaTec's Professional Services.

Manufactured by: ConvaTec Limited Decside CH5 2NU, UK

ConvaTec A Division of E. R. Squibb & Sons, L.L.C. Princeton, NJ 08543 1-800-422-8811

Distributed in Canada by: ConvaTec Division of/de Bristol-Myers Squibb Canada, Co. Montréal, Québec, Canada 1-800-465-6302

ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd Level 1, 352 Wellington Rd Mulgrave VICTORIA 3170 Free Call 1800 335 276 61 3 8562 1300

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February 8, 2008

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2007 Annual Meeting San Diego, California

Proceedings

Meeting Dates February 14-18, 2007

Exhibit Dates February 14-16, 2007



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emoral stem and Ring Loc acetabular shell were assessed at a minimum of 60 (mean of 89.5 \pm 9.6) months for acetabular adjethylene wear by an independent observer (JMM) unaware that acetabular inclination and offset were the parameters being assessed. All x-rays were measured for restoration of femoral offset and acetabular inclination using Matlab (Math Works, Inc. Natick, MA). Wear was analyzed against acetabular inclination and restoration of lemoral offset using SPSS12.0 (Chicago, (β). Mean linear wear for all patients was 0.12 ± 0.1 millimeters per year and mean volumetric wear was 56.1 ± 5.5 millimeters per year. Patients with acetabular inclination over 45 degrees had mean linear wear rates of 0.16 ± 0.03 millimeters per year compared to 0.09 \pm 0.01 millimeters per year if the inclination angle was less than 45 degrees (p<0.001). Patients with offset restored to within 5 millimeters had mean linear wear rates of 0.09 ± 0.02 millimeters per year compared to all others with 0.13 ± 0.03 millimeters per year (p<0.06). Acetabular inclination 45° proved to be an important factor with regards polyethylene wear with significantly increased (p<0.001). A strong trend (p = 0.06) was noted for less wear in cups with restored femoral offset.

POSTER NO. PO36

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Cup Inclination Angle and Whole Blood Levels of Cobalt and Chromium lons After hip resurfacing

Alister Hart, FRCS, London, United Kingdom (*)

Pranai Buddhev, BSc (*)

Payam Tarassoli, BSc (*)

Jonathan Powell, PhD (*)

nter to page if

John Skinner, FRCS, London, United Kingdom (*)

Abstract: In vitro, the factors that determine wear particle volume from metal-on-metal (MOM) hip resurfacing include: head size, dearance, surface roughness and carbide density. However, in vivo there are additional factors including: bilateral implants and time from operation. Studies of metal on polyethylene bearings show an association between wear and acetabular inclination, but there is no published correlation for metal on metal bearings. Using standardised radiographs, we measured the indination angle (using UTHSCSA image tool) of the acetabular components in thirty-one patients (mean age 54 years) who underwent unilateral Birmingham hip resurfacing (mean time post operation of 22 months). We measured whole blood chromium and cobait ions using inductively coupled mass spectrometry (detection limit 10 parts per trillion). All components were well fixed. There was a positive correlation between the acetabular inclination angle (range 28° - 55°) and whole blood concentration of Cobalt (range 2.3 - 7 mcg/L), Chromium (range 0.56 - 4.3 mcg/L) and total metal ion levels (range 3.1 -10.3 mcg/1.). This finding was statistically significant, with a Pearson correlation coefficient of 0.46 (95% Cl 0.13-0.70) and a p-value of 0.00398. Acetabular inclination angle is likely to be a factor in determining the metal ion level following hip resurfacing. We identified a threshold level of 50° inclination, after which metal ion levels rise dramatically. We recommend surgeons implant the metal socket at an inclination angle of less than 50°.

POSTER NO. P037

Comparison of the Skin Blood Flow Between Mini and Conventional Incision Approaches During THA

Takahiko Kiyama, MD, Fukuoka, Japan (n) Masatoshi Naito, MD, Fukuoka, Japan (n) Yuichiro Akiyoshi, MD, Fukuoka, Japan (n) Hiroshi Shitama, MD, Fukuoka, Japan (n) Takafumi Kumano, MD, Fukuoka, Japan (n) Tsuyoshi Shinoda, MD, Fukuoka, Japan (n) Akira Maeyama, MD, Fukuoka, Japan (n) Akinori Takeyama, MD, Fukuoka City, Japan (n) Xie Jun, MD, Fukuoka City, Japan (n)

Abstract: In order to clarify the effects of the length of incision on the local circulation, we measured the skin blood flow in vivo during total hip arthroplasty. The patients were randomly allocated to have a surgery through either a mini incision of 7 cm (group-M) or a conventional incision of 14 cm (group-C). Twenty patients who underwent total hip arthroplasty were investigated. 10 patients were operated through the mini incision whereas the remaining 10 patients were operated through the conventional incision THA. A laser Doppler flowmetry was utilized to measure the intraoperative blood flow of the skin. The measurements were performed at two regions, namely anterior and posterior regions across the incision. As a control, the skin blood flow over the anterior superior iliac spine was measured. The measurements were performed before making a skin incision and after implantation, respectively. In the group M, the average value of skin blood flow at anterior region was decreased from 2.4 ml/min/100g to 1.6 (p<0.05), and that at posterior region was decreased from 2.2 to 1.5 (p<0.05). While, those values in the group C changed from 3.2 to 2.9 at anterior (N.S.) and from 3.3 to 3.2 at posterior regions (N.S.). The values of control were constant in both groups during operation. The skin blood flow in mini incision THA was significantly decreased during operation. The reduction of this skin circulation may be caused due to the excessive forces applied to the tissue by retractors to expose the hip joint.

POSTER NO. PO38

The Jubilee Method: A Novel, Effective Wound **Dressing Following THR and TKR**

John Dillon, MRCS, Glasgow, United Kingdom (n) Jon Clarke, MBChB (n)

Andrew Kinninmonth, FRCS (n)

Abstract: Modern dressings - such as Molndal (2002) - have been shown to be more effective than standard dressings. They reduce patient morbidity due to wound healing problems such as blistering, frequent and early dressing changes, and potentially avoid prolonged hospitalization. The Jubilee Method is a novel wound dressing based upon Molndal, consisting of Aquacel and Duoderm extrathin. Its efficacy has been evaluated in this study by comparison to a standard dressing (Aquacel and Mepore). A prospective, randomized controlled trial was conducted involving 400 patients undergoing primary elective total hip (IHR) or total knee (TKR) arthroplasty. Patients were randomized to receive one of the two dressings. Incidence of blistering, surgical-site infection (SSI) rate, number of dressing changes, day of first dressing change, and delayed discharge due to wound problems were noted. 380 forms were successfully completed. The incidence of blistering was 1.9% in the Jubilee group, and 19.1% in the Standard group. First day dressing change was 3.77 in the Jubilee group, compared with 2.26 in Standard group.

or employee, and n-no conflicts disclosed. For full

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Total mean number of dressings was 1.57 for Jubilee, and 3.2 Standard. Delayed discharge due to wound problems was 1.9% Jubilee, and 8.7% Standard. SSI rates were 0.4% Jubilee, and 1.9% Standard. The Jubilee method group demonstrated a later first day dressing change, fewer dressing changes, less blistering, fewer delayed discharges, and a lower SSI rate compared to the standard dressing. The Jubilee method is a highly effective dressing in primary total knee and total hip arthroplasty procedures.

POSTER NO. P039

Do Hooded Acetabular Liners Increase the Incidence of Prosthetic Impingement After THR?

Molly M Usrey, BS, Houston, TX (a – Plus Orthopedics) Lanny Joseph Rudner, MD, Houston, TX

(a – Plus Orthopedics)

Philip C Noble, PhD, Houston, TX (a, b, c, e – Plus Orthopedics, Zimmer, a, c – Stryker, a, b – Medtronic) Michael A Conditt, PhD, Houston, TX (a – Plus Orthopedics)

Michael V Birman, MD, Ann Arbor, MI

(a – Plus Orthopedics)

Richard F Santore, MD, San Diego, CA

(a – Plus Orthopedics)

Kenneth B Mathis, MD, Houston, TX

(a, e - Plus Orthopedics)

Abstract: Impingement of the femoral neck on the acetabular liner is a function of joint range of motion, implant head:neck ratio, and acetabular liner design and position. Hooded acetabular liners are frequently used to increase joint stability, but can potentially increase the probability of impingement if the liner is malpositioned. As such, there is uncertainty over the utility of hooded acetabular liners. 113 acetabular components were retrieved during revision total hip arthroplasty after an average time in situ of 76 months. Each acetabular liner was examined with incident light and inspected for presence, location, and severity of signs of impingement. The presence of a liner hood along with angle, height, and type of hood were recorded. The depth of penetration of the femoral head into the acetabular liner was also measured. Approximately one-third (34%;38/113) of the liners examined had impingement damage graded as moderate or severe. Impingement was only slightly more prevalent in hooded liners compared to neutral liners (35% vs. 29%). In the hooded liners examined, the site of impingement was located on the elevated portion of the rim in 85% (44/52) of components, and was restricted to the neutral portion in only 8 of the liners examined (15%; 8/52). Hooded liners with impingement damage displayed three times the depth of head penetration in the liner than those without impingement (1.56mm vs 0.52mm). This study demonstrates that hooded liners rately function as intended. Though it has been assumed that hooded liners increase head containment without neck/liner impingement, in practice, a far more common scenario is impingement of the neck on the elevated section of the liner leading to significant surface damage and reduced range-of-motion. This suggests that improved designs and surgical guidelines are needed to enable correct placement of the elevated segment of hooded liners to minimize unexpected impingement, and maximize head coverage during episodes of instability.

POSTER NO. PO40

Five to twelve year follow-up of hip resurfacing in patients under the age of 55 with osteoarthritis

Joseph Daniel, FRCS, Birmingham, United Kingdom Chandra Pradhan, FRCS, Birmingham, United Kingdom Hena Ziaee, BSc, Birmingham, United Kingdom Pynsent Paul, PhD, Birmingham, United Kingdom

Derek J.W. McMinn, FRCS, Birmingham, United Kingdom Abstract: The results of conventional hip replacements are worse in young patients than in other groups. Hip resurfacing is a bone conserving option and has been showing encouraging early results from several centres. Continued monitoring of early cohorts of resurfacings will reveal their medium and long-term survival. This is a retrospective study of two cohorts of patients under the age of 55 with osteoarthritis treated with hybrid-fixed metal-metal resurfacings. The cohorts are a) 43 consecutive hips treated by the senior author in 1994 and 95 with a hydroxyapatitecoated smooth uncernented cup and a cemented femoral component and b) 403 consecutive patients treated with hydroxyapatite-coated porous uncemented cup and a cemented femoral component between 1997 and 2001. Mean age at operation was 48.3 years. Ten patients (11 hips) died from unrelated causes. Out of the remaining 435 hips (374 patients) at a followup of 5 to 12 years (mean 7.1 years), there was one failure (cumulative failure rate 0.2% at 12 years) from avascular necrosis of the femoral head. The mean Oxford score of the 374 patients (434 hips) is 13.4. 87% had a UCLA score of 7 and above. 55% participated in impact sports or were involved in heavy occupational work. In the present study, excellent survival (99.8%) was seen in spite of high activity level. The extremely low failure rate in the medium term proves the suitability of resurfacing in young active patients. However, caution needs to be exercised until long term results are available.

POSTER NO. PO41

The Results Of Uncemented Total Hip Arthroplasty In Patients with Juvenile Idiopathic Arthritis

Johan Witt, MD, Maida Vale London, United Kingdom (*) Vijayaraj Kannan, MD, London, United Kingdom (*) Abstract: We report the results of a prospective study of uncemented THA in young patients with IIA with a minimum follow-up of two years 54 patients with 78 arthroplasties were available for review. The mean age at operation was 18 years (10, to 29). The average follow up was 6 years (2 to 10). Three different types of stem were used depending on size and anatomy. Three different uncemented cups were used and in 4cases a support ring and cemented cup was used. The hips were graded before surgery and at follow-up using the Hospital for Special Surgery scoring system. The mean improvement in the pain score was 6.3 and the total score improved from and average of 15 to 32. Overall a revision procedure was required in 7 hips. Liner revision was performed in 4 hips. Two cups were revised for loosening (1 SROM and 1 reinforcement ring) and 1 stem (SROM) which had never osseointegrated. In the remaining hips radiographic analysis revealed well osseointe grated stems in 74 hips. There was stable subsidence of 1 CADCAM stem not requiring revision, and subsidence of 2CADCAM stems due for revision (8yrs post-op). Radiolucent lines were seen around 3 cups (SROM) and 1 support ring. The remaining 72 cups demonstrated good osseointegration. This study shows a lower revision rate and better radiographic appearance compared to previous reports with similar follow up of THA in Juvenile Idiopathic Arthritis.

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• In CDA has not cleared the drug and/or medical device for the use cleareded in this presentation (i.e. the drug or medical device is being discussed for an off label use). For full information, for any other is a second device in the drug or medical device is being discussed for an off label use).

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SECTION 21: OTHER

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

Form FDA-3674 follows this cover sheet.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration



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Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(Fe	or submission with an application/submission, including amendments, sup ederal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service	plements, and resubn Act.)	nissions, under §§ 505, 515, 520(m	i), or 510(k) of the
	SPONSOR / APPLICANT / S	SUBMITTER INFOR	RMATION	
1.	NAME OF SPONSOR/APPLICANT/SUBMITTER		2. DATE OF THE APPLICATION	SUBMISSION
	ConvaTec, a Division of E.R. Squibb & Sons, L.L.C.		WHICH THIS CERTIFICATION February 8, 2008	ACCOMPANIES
3.	ADDRESS (Number, Street, State, and ZIP Code)		4. TELEPHONE AND FAX NUME (Include Area Code)	BER
	200 Headquarters Park Drive		908-904-2500	
	Skillman, NJ 08558		(Tel.) <u>908-904-2500</u>	******
			(Fax) 908-904-2235	
····		FORMATION	· · · · · · · · · · · · · · · · · · ·	· · ·
5.	FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietar FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, T (Attach extra pages as necessary)	y and/or Chemical/Bioc rade or Proprietary or M	hemical/Blood/Cellular/Gene Therap lodel Name(s) and/or Model Number	y Product Name(s) (s)
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9.	CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for add		, ,	
	A. I certify that the requirements of 42 U.S.C. § 282(j), Section 40, 110-85, do not apply because the application/submission which t	this certification accom	npanies does not reference any clir	trial.
	B. I certify that the requirements of 42 U.S.C. § 282(j), Section 40, 110-85, do not apply to any clinical trial referenced in the applica			at. 823, Public Law
	C. I certify that the requirements of 42 U.S.C. § 282(j), Section 40.	2(j) of the Public Heal	th Service Act, enacted by 121 St	at. 823, Public Law
	110-85, apply to one or more of the clinical trials referenced i	n the application/subr	nission which this certification acc	companies and that
10	those requirements have been met. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLIN			
10.	UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra	PUBLIC HEALTH SE		
	NCT Number(s):	<u> </u>		
	e undersigned declares, to the best of her/his knowledge, that this is an a			
	ure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section a false certification under such section are prohibited acts under 21 U.S.C.			
	arning: A willfully and knowingly false statement is a criminal offense, U.S.			· · · · · · · · · · · · · · · · · · ·
11.	SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITL	E OF THE PERON WHO SIGNED IN	I NO. 11
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	- Willy Junicity			
		(Title) Associat	e Director, US and International R	egulatory Affairs
13.	ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)	14. TELEPHONE AN (Include Area Co		15. DATE OF CERTIFICATION
	200 Headquarters Park Drive	,	2541	02/08/2008
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Food and Drug Administration Office of Device Evaluation & Office of In Vitro Diagnostics

COVER SHEET	MEMORANDUM
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From:	·Reviewer Name
Subject:	510(k) Number
To:	The Record

Ph NUSC

5 Please list CTS decision code

□ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

X Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.	e., SE, SE with Limita	ations, etc.):	YES	NO
Indications for Use Page	Attach IFU		V_{\prime}	
510(k) Summary /510(k) Statement-	Attach Summary			
Truthful and Accurate Statement.	Must be present for a	Final Decision		
Is the device Class III?		· · · · · · · · · · · · · · · · · · ·		./
If yes, does firm include Class III Summary?	Must be present for a	Final Decision		V.
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarkel REVIATED STANDARDS DATA FORM.DOC)	Notification510kProgra	m/0_4136/ABB	•	
Is this a combination product? (Please specify category, see <u>http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarket</u> <u>MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%2</u>		m/0_413b/CO		\checkmark
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Valida Reprocessed Single-Use Medical Devices, http://www.fda Is this device intended for pediatric use only?				
Is this a prescription device? (If both prescription & OTC, check both boxes.)				
Is clinical data necessary to support the review of this 510(k)? Does this device include an Animal Tissue Source?	<u> </u>	-		
		Contact OSB.		
Is this device subject to Section 522 Postmarket Surveillance (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)		COMBCI COD.		V
Is this device subject to the Tracking Regulation? (Medical D Guidance, <u>http://www.fda.gov/cdrh/comp/guidance/169.ht</u>		Contact OC.		V
Regulation Number Class*	Product	•	,	· ·
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(*If unclassified, see 510(k) Staff)	· · · · ·		L /
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Review: Daniel Kraue	PRSB 6	ipin 2	201	0 <i>8</i> -
(Branch Chief)	(Branch Code) $\langle \langle C \rangle \rangle_{1} \wedge$	(Date)	r	
Final Review: (Division Director)	<u> </u>	S Pr (Date)		

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PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):				
1.	Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)			\checkmark
2.	Is the device exempt from 510(k) by regulation (Please see <u>http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC</u> or subject to enforcement discretion (No regulation - See 510(k) Staff)?			
3.	Does this device type require a PMA by regulation (Please see management.)	?		\checkmark
Questi	ons 4-8 are intended to help you start your revie	w:	YES	NO
4.	Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Sp Screening Checklist, <u>http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDF</u> <u>m/0_4d69/Screening%20Checklist.doc</u>)			
5.	 a. Did the firm request expedited review? (See management,) b. Was expedited review granted? (See Guidance for Industry and FDA Staff: . Expedited Review of Devices for Premarket Submissions, http://www.fda.gov/cdrh/mdufma/guidance/108.html) 		4	1 A
6.	To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		
7.	To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		\bigvee
8.	Does this device have indications or technology the review policy of another branch(es)? (Please contra Guidance for Industry and FDA Staff on Bundling Indications in a Single Submission http://www.fda.gov/cdrh/mdufma/guidance/1215.html	act other branch(es) and see Multiple Devices or Multiple		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration Office of Device Evaluation 9200 Corporate Boulevard Rockville, MD 20850

Premarket Notification [510(k)] Review Traditional/Abbreviated

K080383

Date: May 2, 2008 To: The Record From: David Krause, Ph.D., Expert Biologist & Branch Chief

Office: ODE Division: DGRND/PRSB

510(k) Holder: ConvaTec of Skillman, New Jersey

Device Name: Aquacel® Ag Hydrofiber® & Aquacel® Hydrofiber® Wound Dressings Contact: Marilyn Konicky, Associate Director, US and International Regulatory Affairs Phone: 908-904-2541 Fax: 908-904-2235 Email: Marilyn.konicky@bms.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Aquacel® Ag Hydrofiber® & Aquacel® Hydrofiber® Wound Dressings into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Both Prescription & OTC)	X	F	
Truthful and Accuracy Statement	X	i.	;
510(k) Summary	X		1
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		Х	
Does the device design use software?		x	
Is the device sterile?	Х	•	•
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		x	

The Aquacel Hydrofiber Wound Dressings are soft, sterile, non-woven pad- or ribbon-dressings,

1 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-\$118 which are composed of hydrocolloid fibers made from sodium carboxymethylcellulose. They are conformable to the wound and are absorbent. Once wet, the dressings create a soft gel that is used to maintain a moist wound environment. The Aquacel Ag is the same as the Aquacel Dressing but includes 12 mg of silver (1.2% by weight) for each 4" x 4" dressing.

IV. Indications for Use

Aquacel® Hydrofiber® Wound Dressing OTC: For OTC Use...may be used for abrasions, lacerations, minor cuts and minor scalds and burns.

Aquacel® Hydrofiber® Wound Dressing Rx: Under the supervision of a healthcare professional...may be used for the management of leg ulcers, pressure ulcers (Stage II-IV), diabetic ulcers, surgical wounds (post-operative, donor sites, dermatological), partial thickness (second degree) burns, traumatic or 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, local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites, and management of painful wounds.

Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing OTC: For OTC use...may be used for abrasions, lacerations, minor cuts and minor scalds and burns.

Aquacel® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing Rx: Under the supervision of a healthcare professional...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), 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 and infected wounds.

The proposed indications are almost identical to those cleared for these devices in their predicate submissions by this same manufacturer. These dressings were previously cleared via K943258, K982116 & K063271. The sponsor has added dehisced surgical incisions, surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular), donor sites and infected wounds as a result of clinical trials, which will be reviewed below.

V. Predicate Device Comparison

The subject devices are identical to those cleared via K063271. The only change is the expansion of the indications, which were based on the clinical studies reviewed below.

VI. Labeling

ConvaTec has submitted revised labeling in Marilyn Konicky's email of April 17, 2008. The labeling now conforms with the labeling cleared for similar devices in the past. The only labeling changes have been to describe the new indications and to briefly describe the clinical trials.

VII. Sterilization/Shelf Life/Reuse

These have not changed from the predicate. See K063271 review memo.

VIII. Biocompatibility

No additional biocompatibility is needed. See predicate review memo for K063271.

IX. Software

This product includes no software so no software review is needed.

Version:			
Level of Concern:		195 ha tetad cenarta fun araa moaa.	at 100 hat hat 100 hat aan hat 100 het aan aan
		Yes	No
Software description:			
Device Hazard Analysis:	A Labolation of a specific population and and a specific		•
Software Requirements Specifications:			
Architecture Design Chart:			
Design Specifications:			
Traceability Analysis/Matrix:	anna ann ann ann an ann ann ann ann ann		1
Development:			
Verification & Validation Testing:			4 4 4
Revision level history:	n araan ah		1 1
Unresolved anomalies:	a na 1996 a 1996 a 1996 a 1997 a 1997 a 1997 a 1997 a 1997 a 1997		1

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This issue is not applicable to this device.

XI. <u>Performance Testing – Bench</u>

Since these dressings are identical to those cleared in K063271, no additional bench testing was necessary.

XII. Performance Testing - Animal

Since these dressings are identical to those cleared in K063271, no additional bench testing was necessary.

XIII. Performance Testing – Clinical

ConvaTec has provided the results of three clinical trials in which Aquacel (conventional and silver dressings) were compared to predicate dressings following various medical procedures. These studies are summarized below:





XIV. Substantial Equivalence Discussion

		Yes	No	
1.	Same Indication Statement?		Х	If YES = Go To 3
2.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	NA		If YES = Stop NSE
3.	Same Technological Characteristics?	X		If YES = Go To 5
4.	Could The New Characteristics Affect Safety Or Effectiveness?	NA		If YES = Go To 6
5.	Descriptive Characteristics Precise Enough?	X		If NO = Go To 8 If YES = Stop SE
6.	New Types Of Safety Or Effectiveness Questions?	1		If YES = Stop NSE
7.	Accepted Scientific Methods Exist?	!		If NO = Stop NSE
8.	Performance Data Available?	,		If NO = Request Data
9.	Data Demonstrate Equivalence?	1		Final Decision:

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MI.

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWC HART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

- 1. Explain how the new indication differs from the predicate device's indication: *They have added wording regarding a few new types of wounds tested for in clinical trials.*
- 2. Explain why there is or is not a new effect or safety or effectiveness issue:

- 3. Describe the new technological characteristics:
- 4. Explain how new characteristics could or could not affect safety or effectiveness:
- 5. Explain how descriptive characteristics are not precise enough:
- 6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
- 7. Explain why existing scientific methods can not be used:
- 8. Explain what performance data is needed:
- 9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

All issues were resolved through phone calls and email.

XVI. Contact History

Ma (b) (b)	arch 26, 2008: I sent the sponsor representative)(4))(4)	king her to modify the April 17, 2008 with	
Ap wit	o ril 17, 2008: Requested (b)(4) th (b)(4)	on April 17, 2008.	. Sponsor responded
	oril 18, 2008: Requested a few additional ^{(b)(4)} ovided on April 21, 2008.		/. These were
Ма	ay 1, 2008: Requested an additional revision to	(b)(4)	
All	l issues were resolved.		
XVII.	Recommendation Regulation Number: None Regulation Name: None Regulatory Class: Unclassified Product Code: FRO, Wound dressing with a dr	rug	
M	-0V		

Expert Biologist & Branch Chief

Mar 2, 2009 Date

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

510(K) MEMORANDUM

TO: K063271/S2

FROM: Biologist ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: April 12, 2007

SUBJ: ConvaTec, Division of ER Squibb & Sons, LLC 200 Headquarters Park Drive Skillman, NJ 08558 Marilyn Konicky (908)-904-2541 Office (908)-904-2235 Fax

Recommendation: Substantially Equivalent

Procode: NAC and FRO Class: I and unclassified Regulation name: Hydrophillic Wound Dressing Regulation Number: 878.4018

REVIEW:

The application was received in the division on October 30, 2006. I received this document on November 3, 2006. A request for additional information was sent on December 26, 2006 and the company responded on January 26, 2007. A second request for additional information was made on February 28, 2007. A face-to-face meeting took place on March 23, 2007. The company responded to the 2nd AI letter on April 10, 2007. The application is recommended for SE on April 12, 2007.

This is a bundled 510(k) application for Aquacel and Aquacel AG. These two products have been previously cleared under K943258, K982116 and K013814. ConvaTec is submitting this application in effort to receive an expanded indication for pain relief. ConvaTec was advised via 513(g) application C050129, that clinical data would be required to support such a claim for pain relief.

According to the company, Aquacel and Aquacel AG have not changed in terms of their components, composition, method of sterilization, or manufacturing. Therefore, this review will focus on the labeling and the submitted clinical data to determine substantial equivalence for the expanded pain indication. In this application, the company has supplied clinical data in the form of (b)(4)

1 of 11

12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

statement.

The reviewer agrees with this

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1. <u>Comparison of the Intended Use/Indications of the Subject Device and</u> <u>Predicate(s)</u>

<u>Subject Device: Aquacel Hydrofiber Dressing (K982116) and Aquacel Hydrofiber</u> <u>AG (K013814)</u>

Proposed Aquacel IFU:

For Over-The-Counter use, Aquacel Hydrofiber Wound Dressing may be used for: abrasions, lacerations, minor cuts and minor scalds and bums.

Under the supervision of a health care professional Aquacel maybe used for wounds such as:

- leg ulcers, pressure ulcers (Stages I-IV), and diabetic ulcers;
- surgical wounds (post-operative donor sites, dermatological),
- bums (first and second degree);

May also be used for the management of:

- surgical or traumatic wounds that have been left to heal by secondary intention
- local management of wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds
- painful wounds

Proposed Aquacel AG IFU:

For the OTC:

Aquacel AG Wound Dressing may be used for minor abrasions, lacerations, minor cuts, minor scalds and burns.

Under the supervision of a health care professional:

Aquacel Wound Dressing is an effective barrier to bacterial penetration, which may help reduce infection in 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 intent, traumatic wounds,
- wounds that are prone to bleeding such as wounds that have been mechanically or
 - surgically debrided
- oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi sarcoma and angiosarcoma.
- Management of painful wounds

Presently Cleared Aquacel IFU (K982116):

For Over-The-Counter use, Aquacel Hydrofiber Wound Dressing may be used for: abrasions, lacerations, minor cuts and minor scalds and burns. Under the supervision of a health care professional Aquacel maybe used for wounds such as: leg ulcers, pressure ulcers (Stages I-IV), and diabetic ulcers; surgical wounds (post-operative donor sites, dermatological), burns (first and second degree); management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds.

Presently Cleared Aquacel AG IFU (K013814);

For the OTC; Absorbent Antimicrobial Wound Dressing may be used for minor abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a health care professional: Absorbent Antimicrobial Wound Dressing is an effective barrier to bacterial penetration, which may help reduce infection in 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 intent, traumatic wounds, wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided oncology wounds with exudate such as fungoides-cutancous tumors, fungating carcinoma, cutaneous metastasis, Kaposi sarcoma and angiosarcoma.

Predicate device: Mepitel Non-Adherent Silicone Dressing (K984371)

Designed for a wide range of traumatic wounds such as skin tears, abrasions, lacerations, leg ulcers, pressure ulcers, diabetic ulcers, surgical incisions, second degree burns, partial and full thickness grafts intended for the management of painful wounds.



Discussion of whether the intended use/indications are the same:

for the subject device is

acceptable and is considered the same as the predicate device.

2. <u>Comparison of the Technological Characteristics (Design, Materials, Sizes,</u> <u>Features, Shapes, etc.) of the Subject Device and Predicate(s)</u>

Subject Device

No changes have been made to Aquacel or Aquacel AG in terms of its components or composition. Aquacel is classified as a hydrocolloid (CFR 878.4018 hydrophilic dressings). The company has added the trademark name of "hydrofiber" to further denote Aquacel.

Aquacel is a soft, sterile, non-adherent, non-woven highly absorbent fibrous wound dressing and filler composed of sodium carboxymethylcellulose. It has the appearance of a white needled fabric. Upon absorption of wound exudate, it forms a cohesive gel which provides a soft, moist wound interface and is easily removed with little or no damage to healing tissues.

Dressing pads are available in the following approximate sizes: (5 cm x 5 cm) (10 cm x 10 cm) (15 cm x 15 cm) (15 cm x 20 cm) (20 cm x 30 cm). Additionally, a ribbon/rope presentation is available, approximately: (2 cm x 30 cm)

Aquacel Ag® is a silver impregnated antimicrobial dressing that is soft, sterile, nonwoven pad composed of sodium carboxymethylcellulose and 1.2 % ionic silver which allows for

12mg of silver per 4 x 4 inch dressing. It is available in sizes ranging from 2" x 2" to 8" x 12". Sodium Carboxymethylcellulose is produced as a textile fiber and presented in the form of a fleece held together by a needle bonding process. The hydrofiber dressing is capable of absorbing large amounts of wound exudates and bacteria, supporting a moist healing environment and aids in the removal of nonviable tissue from the wound. The dressing absorbs and interacts with wound exudates to form a soft, hydrophilic, gas permeable gel that traps bacteria and conforms to the wound contours. The dressing provides a sustained release of silver ions for up to 14 days. Both Aquacel and Aquacel AG use a secondary dressing

Predicate Device(s)

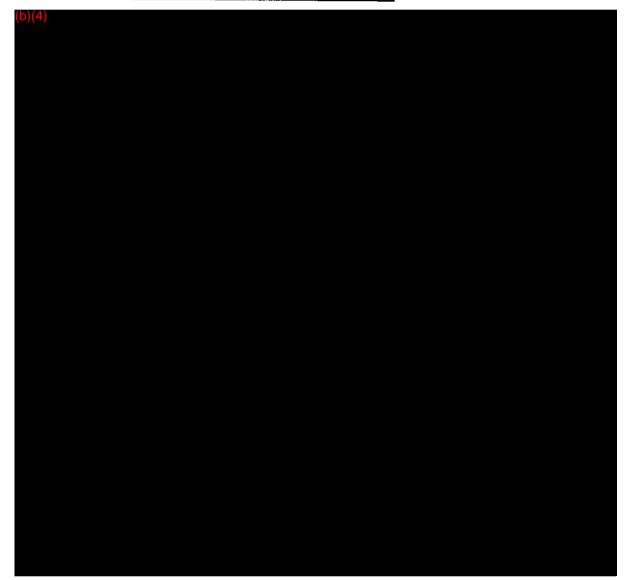
The Mepitel Non-adherent Silicone dressing is described as a sterile, single use, nonadherent wound dressing composed of a silicone-coated polyamide netting. The dressing is intended as a primary dressing which supports the tissue and acts as a cushion between an absorbent secondary dressing and the skin/wounds.

Discussion of whether the subject device has a significant change in technological characteristics.

Again, no changes have been made to Aquacel or Aquacel AG since the initial clearance in terms of its components or composition; these two devices were cleared via the 510(k) process. The question is whether Aquacel/Aquacel AG and Mepitel are substantially equivalent with respect to pain relief. Mepitel has a claim as part of

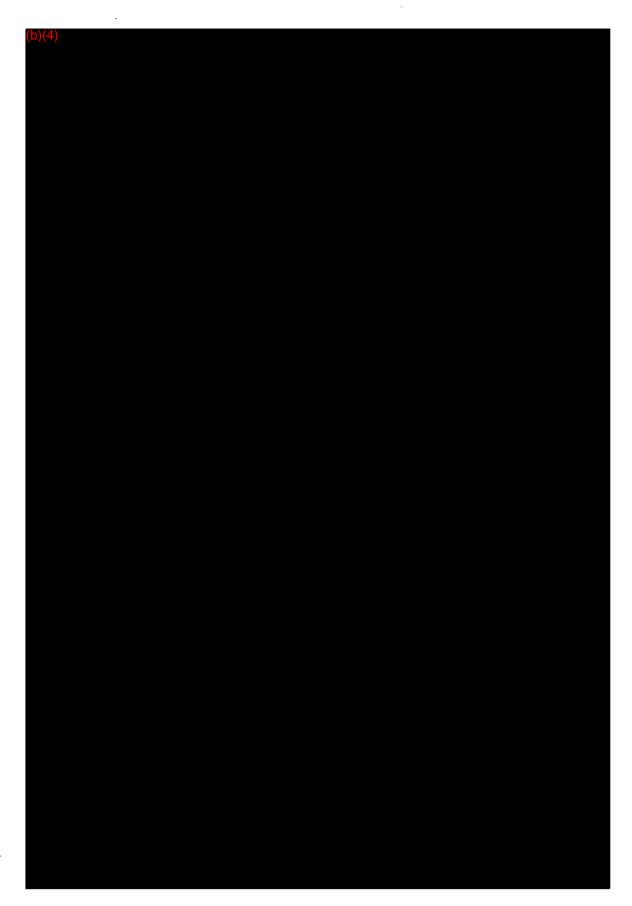
their indications for use that their silicone dressing can provide pain relief during dressing changes. Aquacel would like to make a similar claim.

The device compositions are different, in that, Aquacel is a hydrocolloid made of sodium carboxy methylcellulose (Aquacel AG additionally contains 1.2% ionic silver) and Mepitel is made of silicone and a polyamide tricot net. Both devices are supplied sterile and can be kept in place for several days. The modes of action for pain relief are similar between the two devices, both devices are non-adherent to the wound which minimizes trauma and pain during dressing changes. It should be noted, there is no chemical that induces the pain relief, it is merely the non-adherence to the wound bed that prevents pain caused by dressing changes. Although the components of the subject device and the predicate device differ, the mode of action with respect to pain relief is similar.



3. Comparative Data (in vitro, animal and/or clinical)

••



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Does the product contain drugs or biologicals? No, the product is deemed a device.

4. Sterilization - "http://www.fda.gov/cdrh/ode/guidance/361.html"

Packaging: The dressing is packaged in a (b)(4) (b)(4)	
(b)(4) ±	
(b)(4)	

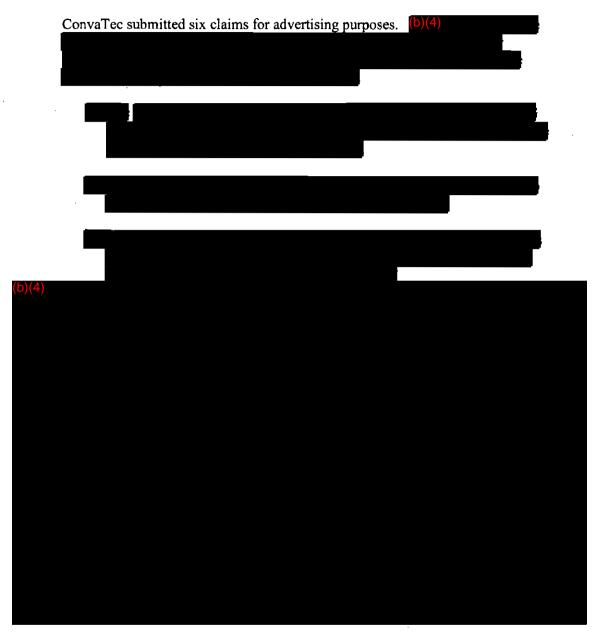
5. Discussion of Labeling Adequacy

OTC and/or Prescription: OTC but available by prescription for burn patients Package Insert: Section I

Carton/Pouch Labels: Product labeling submitted but not the actual pouch label

6. Labeling claims

...



The following claim appears in their device description. This claim was also in their device description in K013814.



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-&18

.



7. <u>Has sponsor provided all administrative requirements?</u>

- Truthful and Accurate Statement page 40
- 510(k) Summary or Statement pages 33-36
- Indication for Use Page pages 31-32

..

• FDA Establishment Registration Number: 2241599

8. Analysis of the Equivalence of the Subject and Predicate(s)



Therefore, Aquacel and Aquacel AG are substantially equivalent to the predicate device in terms of their pain indication.

9. Contact History/Requests for More Information:

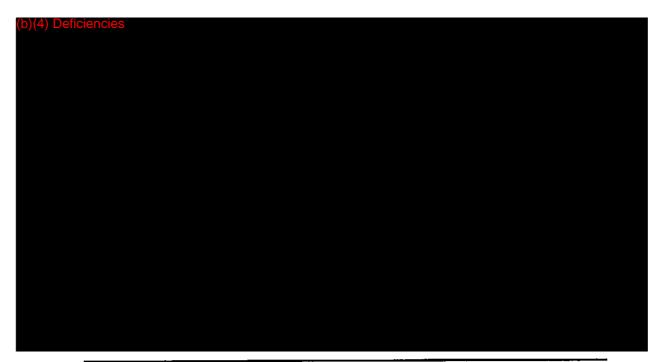
The following deficiencies were sent to the company in an AI letter, December 19, 2006.



(b)(4) Deficiencies

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

.,



(b)(4) Deficiencies		

April 12, 2007 All issues have been addressed. I recommend this subject device can be found substantially equivalent to the predicate device with regards to the management of painful wounds.

12 Stanl 07 Date Name Plastic and Reconstructive Surgery Devices Branch (8 22 11 of 11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Minutes: ConvaTec Meeting with FDA

Date:	26 March 2007
Location:	20C, 9200 Corporate Blvd., Rockville, MD 20817
Subject:	Labeling Issues: Necessity for clinical evidence for Drug Claims
Device:	Aquacel Hydrofiber Wound Dressing and Aquacel AG Hydrofiber with
	Silver Impregnated Wound Dressing
Application:	K013814, K063271

FDA Attendees:

(b) (6)	, VP, Reg Aff
(b)(6)	, Dir, Reg
(b)(6)	, Director, Anti-Infectives
(b)(6)	, Legal Counsel
(b)(6)	, Assoc Director, Reg
GRND	
Via teleco	onference:
	, Chief Scientific Officer
	(b)(6) (b)(6) (b)(6) (b)(6) GRND

ConvaTec Attendees:



Next Steps:

• Sponsor will submit a response to the Additional Information request

Suzanne Malli, BA, BSN, Reviewer, PRSB Capt. Stephen Rhodes, Branch Chief, PRSB 23

Krause, David

From:	(b)(4)	
Sent:	Thursday, May 01, 2008 4:35 PM	
То:	Krause, David	
Cc:	(b)(6)	
Subject:	K080383 - AQUACEL Dressings and AQUACEL Ag Dressings	
Attachments: (b)(4)		

Dear Dr. Krause,

In response to your email of today, May 1, 2008, I am forwarding to you the following documents:

(b)(4)

• A cover letter which outlines the requested changes.

Please note, as mentioned in the cover letter, that the (b)(4)

Please let me know if you have any questions.

Best regards, Marilyn Konicky



200 Headquarters Park Drive Skillman, NJ 08558 908 904-5200

May 1, 2008

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

RE: K080383

AQUACEL® Hydrofiber® Wound Dressing AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

Dear Sir or Madam:

Accompanying this letter please find the following attachment, as requested by Dr. David Krause, reviewer of the subject bundled 510(k):

(b)(4)

We trust you will find this information satisfactory, and the 510(k) submission will be cleared. If, however, you have any questions, please contact me at (908)-904-2541 or by fax at (908)-904-2235 or via email at <u>marilyn.konicky@bms.com</u>.

	Sincerely,	(b)(6)	ı	
(b)(6)				
	Associate L	urector		

US and International Regulatory Affairs

AQUACEL[®] and AQUACEL[®] Ag

Revised May 1, 2008

SECTION 4: INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K080383

Device name: AQUACEL[®] Hydrofiber[®] Wound Dressing

For Over-the-Counter Use, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for the management of:

- Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- Surgical wounds (post-operative, donor sites, dermatological)
- Partial thickness (second degree) burns
- Traumatic or surgical wounds left to heal by secondary intention such as dehisced surgical incisions¹
- Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹
- Traumatic wounds²
- Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Management of painful wounds

¹ Clarified / New Indication, not previously included in the format under K943258, K982116, or K063271

²Indication re-positioned within Indications for Use statement

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use X (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)

AQUACEL[®] and AQUACEL[®] Ag

Revised May 1, 2008

SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED

510(K) Number (if known): K080383

Device names: AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

For Over-the-Counter Use, AQUACEL[®] Hydrofiber[®] Wound Dressing may be used for:

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

Indications for Use:

Under the supervision of a healthcare professional, AQUACEL[®] Ag Hydrofiber Dressing 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 incisions¹
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular)¹
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites¹
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- Infected Wounds¹

¹Clarified / New Indication, not previously included in this format under K013814 or K063271

Prescription Use <u>X</u>	AND/OR	Over-the-Counter UseX
(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)

Additional Modifications Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

Krause, David

From:	(b)(4)
Sent:	Monday, April 21, 2008 4:30 PM
To:	Krause, David
Cc:	(b)(6)
Subject:	Re: Additional Modifications - K080383 - AQUACEL and AQUACEL Ag Dressings
Attachmen	
Dear Dr. Kra	use,

Attached for your review please find the amended Section (b)(4)

I trust you will find this information satisfactory. Please let me know if you have additional questions, or require additional information.

Best regards, Marilyn

Krause, David wrote:

Marilyn,



David

.

AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

SECTION 5: 510(k) SUMMARY

AQUACEL[®] Hydrofiber[®] Wound Dressing

Applicant:	ConvaTec A Division of E. R. Squibb & Sons, LLC 200 Headquarters Park Drive Skillman, New Jersey 08558	
Contact:	Marilyn Konicky Associate Director, US and International Regulatory Affairs 908-904-2541 fax: 908-904-2235 email: marilyn.konicky@bms.com	
Device:	AQUACEL [®] Hydrofiber [®] Wound Dressing	
Classification Name: Dressing, Wound, Hydrophilic		
Device Class:	Class I	
Product Code:	NAC	
Substantially Franciscolor & Destance A OLLA OPL® 14 1 CL ® 14		

Substantially Equivalent Device: AQUACEL[®] Hydrofiber[®] Wound Dressing K943258, K982116, K063271

AQUACEL[®]Hydrofiber[®] Wound Dressings are soft, sterile, non-woven pad or ribbon dressings composed of hydrocolloid fibers (sodium carboxymethylcellulose). These conformable and highly absorbent dressings absorb wound fluids and create a soft gel which maintains a moist environment which supports the body's healing process.

AQUACEL[®] dressing is indicated for the management of wounds and can be used overthe-counter for minor wounds such as abrasions, lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AQUACEL[®] dressing may be used for more serious wounds such as leg ulcers, pressure ulcers (Stages II-IV), diabetic ulcers, surgical wounds, donor sites, second degree burns, wounds that are prone to bleeding and the management of painful wounds.

The Hydrofiber[®] technology in AQUACEL[®] dressings aids in removing necrotic material from the wound without damaging newly formed tissue. AQUACEL[®] dressings are currently indicated for the management of post-operative surgical wounds and surgical or traumatic wounds that have been left to heal by secondary intention.

AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

A majority of post-operative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of nonadherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

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. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL[®] which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber[®] dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintains a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using AQUACEL[®] leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of AQUACEL[®] dressings in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber[®] based products can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL[®] hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL[®] / Tegaderm[™] to control treatment. AQUACEL[®] / Tegaderm[™] was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL[®] / Tegaderm[™] and 98 patients to control) and the results demonstrated that AQUACEL[®] / Tegaderm[™] was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; p<0.00001). Dressing pain score was statistically lower for patients on AQUACEL[®] / Tegaderm[™] dressing compared to control¹ (p<0.001). AQUACEL[®] was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL[®] hydrofiber dressing group and 31 patients to the control group). Dressing

AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

changes were required in (43%) patients in the AQUACEL[®] hydrofiber dressing group compared to (77%) patients in the control group (p=0.001)². In addition, the use of AQUACEL[®] hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL[®] hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL[®] hydrofiber dressing potentially limiting mechanical irritation and damage to the wound³. In conclusion, the studies demonstrate that AQUACEL[®] hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references.

<u>References</u>

- 1. Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL[®] and Tegaderm[™] versus Cutiplast*. *Ann R Coll Surg Engl* 2006; 88: 18-22
- 2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber[®] and central pad dressing. *Int Wound J* 2006; 3; 133-137
- 3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

*Cutiplast is a trademark of Smith & Nephew Tegaderm[™] is a trademark of 3M Company

AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing are registered trademarks of E.R. Squibb & Sons, L.L.C.

AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

SECTION 5: 510(k) SUMMARY

AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing

Applicant:	ConvaTec A Division of E. R. Squibb & Sons, LLC •200 Headquarters Park Drive Skillman, New Jersey 08558		
Contact:	Marilyn Konicky Associate Director, US and International Regulatory Affairs 908-904-2541 fax: 908-904-2235 email: marilyn.konicky@bms.com		
Device:	AQUACEL [®] Ag with Hydrofiber [®] Silver Impregnated Antimicrobial Dressing		
Classification Name: Dressing, Wound, Drug			
Device Class:	Unclassified		
Product Code:	FRO		
Substantially Equivalent Device: AOUACEL [®] Hydrofiber [®] Wound Dressing			

Substantially Equivalent Device: AQUACEL[®] Hydrofiber[®] Wound Dressing K943258, K982116, K063271

AQUACEL[®]Ag Hydrofiber[®] (Silver Impregnated Antimicrobial Dressing) is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.

AQUACEL[®] Ag dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions and lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, AQUACEL[®] Ag dressing may be used for more serious wounds such as diabetic foot and leg ulcers, pressure ulcers (partial and full-thickness), surgical wounds or traumatic wounds left to

AQUACEL[®] and AQUACEL[®] Ag

Revised April 21, 2008

heal by secondary intent, and partial thickness burns (second degree), wounds that are prone to bleeding, oncology wounds and management of painful wounds.

AQUACEL® Ag Hydrofiber® Dressing is indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that, as a protocol of care, may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria provided by AQUACEL® Ag Dressings support the body's healing process and help reduce the risk of wound infection.

A majority of postoperative surgical incisions are sutured, stapled or glued and are covered with some form of dressing. This first dressing, frequently referred to as the primary dressing, acts to absorb drainage, maintain a clean environment and serve as a barrier against further trauma to the delicate incision surface. Careful selection of nonadherent, absorptive dressings that do not become incorporated within the incision serves greatly to reduce the potential of surgical incision injury, and reduce pain upon dressing change when the time comes for the initial dressing to be removed.

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. The capacity to absorb, conform and the relative ease of removal are important attributes of AQUACEL[®] Ag, which probably play an important role in healing by primary intent for surgical wounds. Hydrofiber® dressings absorb fluid directly into the body of the dressing, significantly increasing the volume of fluid that can be absorbed – a process called vertical wicking. This process removes excess exudate from the wound, prevents lateral wicking that can cause maceration of the wound edges, but still maintain a moist environment for wound healing. All the studies which have been reviewed suggest that, compared to standard dressings, using a Hydrofiber[®] dressing (AQUACEL[®]) leads to significantly less dressing changes.

In addition, reduction in blister formation, hematoma and edema and decreased pain were observed in some of the studies. It is important to note that a majority of the clinical trials were randomized controlled trials. More importantly, there were no undue safety concerns which were observed in the trials. Although the studies were predominantly in orthopedic surgery, utilization of Hydrofiber[®] dressings (AQUACEL[®]) in vascular surgery also has been discussed.

Based on the evidence provided, we propose that Hydrofiber® based products (AQUACEL® dressings and AQUACEL® Ag dressings) can be used safely and effectively as primary dressings on surgical incisions which heal by primary intent. A brief summary of some of the clinical information follows:

AQUACEL[®] hydrofiber dressing has been shown to be safe and effective as a primary dressing on surgical incisions which heal by primary intent. The studies consisted of randomized, controlled, clinical trials in hip, knee and arthroplasty surgeries comparing the use of AQUACEL[®] / Tegaderm[™] to control treatment. AQUACEL[®] /Tegaderm[™]

5 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification AQUACEL[®] and AQUACEL[®] Ag Revised April 21, 2008

was used as a primary dressing in hip and knee surgeries compared to control in 183 patients (85 patients were randomized to AQUACEL[®] / Tegaderm[™] and 98 patients to control) and the results demonstrated that AQUACEL[®] / Tegaderm[™] was 5.8 times more likely to result in a wound with no complications than control* (95% CI 2.8-12.5; p<0.00001). Dressing pain score was statistically lower for patients on AQUACEL[®] / Tegaderm[™] dressing compared to control¹ (p<0.001). AQUACEL[®] was compared to control treatment when used as a primary dressing for orthopedic wounds left to heal by primary intention following lower limb arthroplasty. This study evaluated the number of dressing changes post surgery in 61 patients (30 patients were allocated to the AQUACEL® hydrofiber dressing group and 31 patients to the control group). Dressing changes were required in (43%) patients in the AQUACEL[®] hydrofiber dressing group compared to (77%) patients in the control group $(p=0.001)^2$. In addition, the use of AQUACEL[®] hydrofiber as a primary dressing was compared to conventional dressings in a randomized clinical trial in 100 hip replacement patients (50 patients were randomized to AQUACEL[®] hydrofiber dressing and 50 patients were randomized to control). In this study, dressing changes were fewer with the use of AQUACEL® hydrofiber dressing potentially limiting mechanical irritation and damage to the wound³. In conclusion, the studies demonstrate that AQUACEL[®] hydrofiber dressing is safe and effective as a primary dressing on surgical incisions which heal by primary intent. For more details regarding the studies, please see the following references:

<u>References</u>

- 1. Ravenscroft MJ, Harker J, Buch KA. A Prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: AQUACEL® and Tegaderm[™] versus Cutiplast*. Ann R Coll Surg Engl 2006; 88: 18-22
- 2. Abuzakuk T, Coward P, Sheneva Y, Kumar S, Skinner JA. The management of wounds following primary lower limb arthroplasty: a prospective randomized study comparing hydrofiber® and central pad dressing. *Int Wound J*.2006; 3; 133-137
- 3. Harle S, Korhonen A, Jyrki A et al. A randomized clinical trial of two different wound dressing materials for hip replacement patients. *Journal of Orthopedic Nursing (2005)* 9, 205-210

Additional clinical information can be found in Section 20: Performance Testing-Clinical.

*Cutiplast is a trademark of Smith & Nephew

Tegaderm[™] is a trademark of 3M Company

AQUACEL[®] Hydrofiber[®] Wound Dressing and AQUACEL[®] Ag with Hydrofiber[®] Silver Impregnated Antimicrobial Dressing are registered trademarks of E.R. Squibb & Sons, L.L.C.

Krause, David

From:	(b)(4)
Sent:	Thursday, April 17, 2008 4:14 PM
То:	Krause, David
Cc:	(b)(6)
Subject:	[Fwd: RE: K080383 - AQUACEL Dressings and AQUACEL Ag Dressings]
Attachments:	(b)(4)

Dear Dr. Krause,

As requested, attached are the updated (b)(4)

(b)(4) .

I trust you will find the attached satisfactory. Please let me know if you have any questions (908-904-2541).

Best regards, Marilyn

------ Original Message -------Subject:RE: K080383 - AQUACEL Dressings and AQUACEL Ag Dressings Date: Thu, 17 Apr 2008 14:36:50 -0400 From:Krause, David <david.krause@fda.hhs.gov> To: b)(4) CC: b)(4) References:

Marilyn,

Thank you, I have received your updates. These are adequate and I should be able to complete my review tomorrow or Monday. Please send me a corrected Indications Page and a corrected 510(k) Summary with the changes discussed.

Thanks!

David

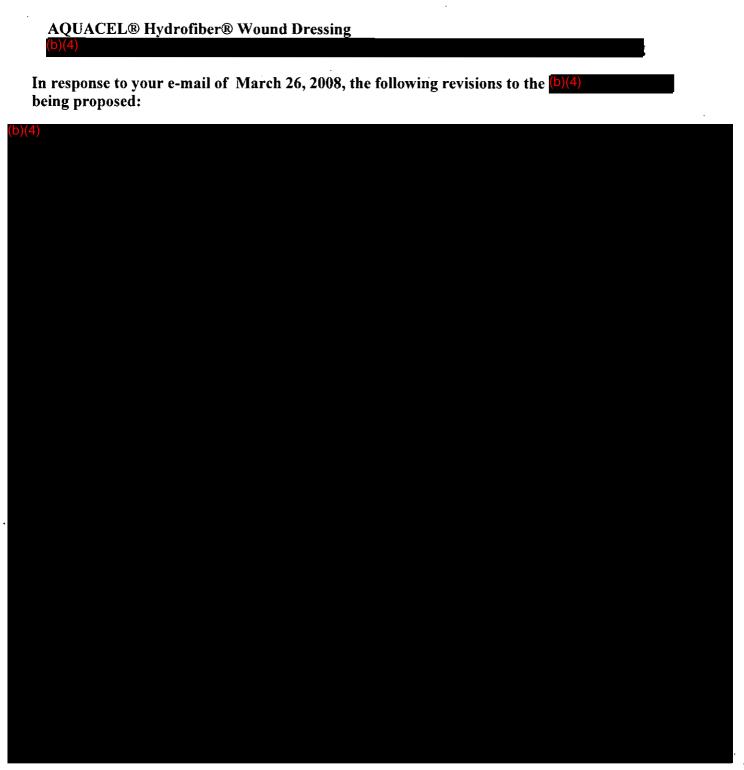
From: **Sent:** Thursday, April 17, 2008 2:30 PM

To: Krause, David Cc^{(b)(4)}

Subject: K080383 - AQUACEL Dressings and AQUACEL Ag Dressings

Dear Dr. Krause,

RE: K080383



ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional indications and claims for these products. We consider this information to be confidential commercial information, and therefore, exempt from public disclosure.

We trust you will find the above satisfactory; however, should you have any questions, please contact me at (908) 904-2541 or via e-mail at <u>marilyn.konicky@bms.com</u>.

Best regards,

Associate Director, Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-81/18 4/18/2008 ConvaTec

Krause, David wrote:

Dear (b) (6)

I have reviewed your 510(k) for the Aquacel and Aquacel Ag Wound Dressings and have a few observations.

Please make these modifications and Email the revised (b)(4) me as soon as possible.

David Krause, Ph.D. Branch Chief Plastic & Reconstructive Surgery Branch to

(b)(4) Draft Document

(b)(4) Draft Document

Krause, David

From:	(b)(4)		
Sent:	Thursday, April 17, 2008 2:42 PM		
То:	Krause, David		
Cc:	(b)(6)		
Subject:	Re: K080383 - AQUACEL Dressings and AQUACEL Ag Dressings		
Attachments(b)(4)			

Dr. Krause,

I will do that as quickly as possible. Again, I do apologize for the delay in getting this information to you.

Best regards, Marilyn

Krause, David wrote:

b)(4)

Thank you, I have received your updates. These are adequate and I should be able to complete my review tomorrow or Monday. Please send me a corrected (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (c)(4) (c)(4)

Thanks!

David

From: (b)(4) Sent: Thursday, April 17, 2008 2:30 PM To: Krause, David Cc: (b)(6) Subject: K080383 - AQUACEL Dressings and AQUACEL Ag Dressings

Dear Dr. Krause,

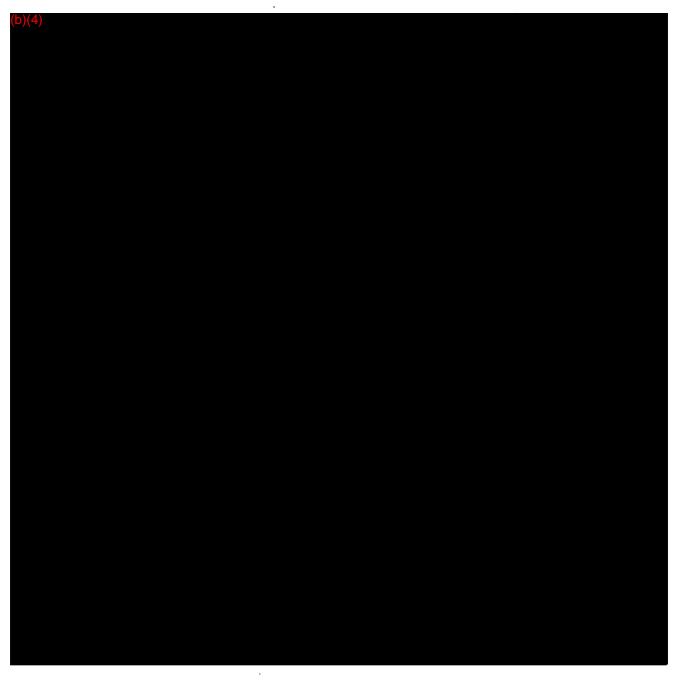
RE: K080383

AQUACEL® Hydrofiber® Wound Dressing AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Wound

Dressing

In response to your e-mail of March 26, 2008, the following revisions to the (b)(4) (b)(4) t are being proposed:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 4/18/2008



ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional indications and claims for these products. We consider this information to be confidential commerical information, and therefore, exempt from public disclosure.

We trust you will find the above satisfactory; however, should you have any questions, please contact me at (b)(4)

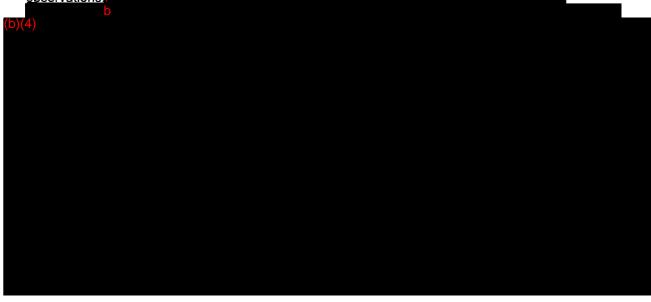
Best regards,

b)(4)

Krause, David wrote:

Dear Ms. Konicky,

I have reviewed your 510(k) for the Aquacel and Aquacel Aq Wound Dressings and have a few observations



Please make these modifications and Email the revised (b)(4) (b)(4) to me as soon as possible.

(D)(4)

David Krause, Ph.D. Branch Chief Plastic & Reconstructive Surgery Branch

,

Krause,	David
110000,	Duna

From:	(b)(4)
Sent:	Thursday, April 17, 2008 2:30 PM
То:	Krause, David
Cc:	(b)(6)
Subject:	K080383 - AQUACEL Dressings and AQUACEL Ag Dressings
Attachments:	(b)(4)

Dear Dr. Krause,

RE: K080383

AQUACEL® Hydrofiber® Wound Dressing AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Wound Dressing

In response to your e-mail of March 26, 2008, the following revisions to (b)(4)	are
being proposed:	•

(b)(4)		

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market these additional indications and claims for these products. We consider this information to be confidential commercial information, and therefore, exempt from public disclosure.

We trust you will find the above satisfactory; however, should you have any questions, please contact me at (908) 904-2541 or via e-mail at <u>marilyn.konicky@bms.com</u>.

Best regards, Marilyn Konicky Associate Director, Regulatory Affairs ConvaTec

Krause, David wrote:

Dear Ms. Konicky,

I have reviewed your 510(k) for the Aquacel and Aquacel Ag Wound Dressings and have a few observations. You

X

Please make these modifications and Email the revised (b)(4) me as soon as possible.

to

David Krause, Ph.D. Branch Chief Plastic & Reconstructive Surgery Branch Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016 510(k) Premarket Notification

 $AQUACEL^{
end{transformation}}$ and $AQUACEL^{
end{transformation}}$ Ag

Revised April 17, 2008

SECTION 13: PROPOSED LABELING

Packaging Components

The individual dressing package and the cartons are unchanged from the previous premarket notification for these products, therefore, they are not being resubmitted at this time.

Package Inserts

Draft package inserts follow for each of the products. The package inserts have also been separated into Over-the-Counter (OTC) and Under the Direction of a Health Care Professional (Rx Only) inserts. The drafts contain the revised Indications for Use sections for each product. Supporting documentation for the additional/clarified indications is included in Section 20 of this submission. The current package inserts are also included and follow the draft package inserts.

Advertising and Promotion

The additional statements to be used in the advertising and promotion of both products are listed below.

AQUACEL[®] and AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

- The gelling properties of Hydrofiber[®] technology protects the incision site and provides for non-traumatic removal of the dressing.
- Absorbs and wicks away drainage.
- Soft and conformable to the incision site.

AQUACEL[®] Ag Hydrofiber[®] Wound Dressing

- In *in vitro* studies on surgical incisions, silver prevents colonization in the dressing and acts to kill micro-organisms, including MRSA and VRE which can cause infection.
- Provides an antimicrobial barrier to the incision site.

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AQUACEL[®] and AQUACEL[®] Ag

Revised April 17, 2008

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- Provides an antimicrobial barrier to the incision site.

(b)(4)