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, 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

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 non-adherent, 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™

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 control[1] ($p<0.001$). 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 wound[3]. 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.

 K080383 page 4 of 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 over-the-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.

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 non-adherent, 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 control[1] ($p<0.001$). 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 wound[3]. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

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 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.

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

Enclosure

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 incisions**[1]
- **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 sites**[1]
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- **Infected Wounds**[1]

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

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383

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 incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- 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**
[2] **Indication 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383

K080383/A

ConvaTec
A Bristol-Myers Squibb Company

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

February 14, 2008

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

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) [redacted], (b)(4) [redacted] (b)(4) [redacted] 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

K25

Marilyn Konicky
Associate Director
US and International Regulatory Affairs

CLINICAL STUDY REPORT

(b)(4)

PROTOCOL NO: (b)(4)

(b)(4) Testing

(b)(4) Testing

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 8-5-08

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K080383/A2

To: Division Director: SU/DGRND

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.

Please review the attached document and return it to the DMC, with one of the statements checked below:

Transfer of Ownership

_____ Information does not change the status of the 510(k); no other action required by the DMC; 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: David Krause

Date: August 8, 2008

POS

K080383/A2

ConvaTec

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

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 contac(b)(4)s (b)(4) (b) Thank you.

Sincerely,

(b)(6)

(b)(6)

Manager, US Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2008

(b)(6)
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,

for Julie A. Stuart

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

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

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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.

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. Melkerson

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

Enclosure

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 incisions**[1]
- **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 sites**[1]
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- **Infected Wounds**[1]

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

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383

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 incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- 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
[2]Indication 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080383

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

February 13, 2008

CONVATEC, A DIVISION OF E.R. SQUIBB
200 HEADQUARTERS PARK DR.
SKILLMAN, NJ 08558
ATTN: MARILYN KONICKY

510(k) Number: K080383
Received: 12-FEB-2008
Product: AQUACEL HYDROFIBER WOUND DRESSING AND AG HYDROFIBER DRESSING

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

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.

Sincerely yours,

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

K080583

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

K3 SU I 115

TABLE OF CONTENTS

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.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CONVATEC
200 HEADQUARTERS PARK DRIVE
SKILLMAN NJ 08558
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
136121983

2. CONTACT NAME
Marilyn Konicky
2.1 E-MAIL ADDRESS
marilyn.konicky@bms.com
2.2 TELEPHONE NUMBER (include Area code)
908-904-2541
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
908-904-2235

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application 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
[ ] 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

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[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 THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support 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

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 16-Nov-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
	(b)(4) (b)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
ConvaTec	2243969		
Division Name *(if applicable)*	Phone Number *(including area code)*		
division of E.R. Squibb & Sons, L.L.C.	(908) 904-2541		
Street Address	FAX Number *(including area code)*		
200 Headquarters Park Drive	(908) 904-2235		
City	State / Province	ZIP/Postal Code	Country
Skillman	New Jersey	08558	USA
Contact Name			
Marilyn Konicky			
Contact Title	Contact E-mail Address		
Associate Director, US and International Regulatory Affairs	marilyn.konicky@bms.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

FORM FDA 3514 (9/07)

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

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)*
- ☐ 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
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ 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
- ☐ 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
- ☐ Other Reason *(specify)*:

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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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NAC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K943258	1	ConvaTec Hydrocolloid Wound Dressing	1	ConvaTec, div. of E.R. Squibb & Sons, LLC
2	K982116	2	AQUACEL Hydrofiber Wound Dressing	2	ConvaTec, div. of E.R. Squibb & Sons, LLC
3	K063271	3	AQUACEL & AQUACEL Ag Wound Dressings (bundled 510(k)	3	ConvaTec, div. of E.R. Squibb & Sons, LLC
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
AQUACEL Wound dressing; Dressing, Wound, Hydrophilic, Class I

	Trade or Proprietary or Model Name for This Device		Model Number
1	AQUACEL Wound Dressing	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K943258	2 K982116	3 K063271	4	5	6
7	8	9	10	11	12

Data Included in Submission
☐ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: NAC
C.F.R. Section *(if applicable)*:
Classification Panel: General and Plastic Surgery Devices
Device Class: ☒ Class I ☐ Class II ☐ Class III ☐ Unclassified

Indications *(from labeling)*

For over-the-counter use: Minor abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, may be used for the management of: leg ulcers, pressure ulecer and diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological); second degree burns; management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding suach as wounds that have ben mechanically or surgically debrided, donor sites and traumatic wounds; management of painful wounds.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)	
Division Name *(if applicable)* (b)(4)		Phone Number *(including area code)* ([redacted]	
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)	
City (b)(4)	State / Province (b)(4)	ZIP/Postal Code (b)(4)	Country (b)(4)
Contact Name (b)(6)	Contact Title Quality Management	Contact E-mail Address (b)(4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4) [redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4) [redacted]

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.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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) **PAGE 5 of 5 PAGES**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
	(b)(4) (b)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
ConvaTec	2243969		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
division of E.R. Squibb & Sons, L.L.C.	(908) 904-2541		
Street Address	**FAX Number *(including area code)***		
200 Headquarters Park Drive	(908) 904-2235		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Skillman	New Jersey	08558	USA
Contact Name			
Marilyn Konicky			
Contact Title	**Contact E-mail Address**		
Associate Director, US and International Regulatory Affairs	marilyn.konicky@bms.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	( )		
Street Address	**FAX Number *(including area code)***		
	( )		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

FORM FDA 3514 (9/07)

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

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)*
- ☐ 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
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ 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
- ☐ 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
- ☐ Other Reason *(specify)*:

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 Hydrofiber Wound Dressing

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2	NAC	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K943258	1	ConvaTec Hydrocolloid Wound Dressing	1	ConvaTec, div. of E.R. Squibb & Sons, LLC
2	K982116	2	AQUACEL Hydrofiber Wound Dressing	2	ConvaTec, div. of E.R. Squibb & Sons, LLC
3	K013814	3	Absorbent Antimicrobial Wound Dressing	3	ConvaTec, div. of E.R. Squibb & Sons, LLC
4	K063271	4	AQUACEL & AQUACEL Ag Wound Dressings (bundled 510(k)	4	ConvaTec, div. of E.R. Squibb & Sons, LLC
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Absorbent Antimicrobial Wound Dressing; AQUACEL Ag; Wound Dressing; Dressing, Wound, Drug; Unclassified
AQUACEL Wound dressing; Dressing, Wound, Hydrophilic, Class I

	Trade or Proprietary or Model Name for This Device		Model Number
1	AQUACEL Ag with Hydrofiber Silver Impregnated Antimicrobial Dressing	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K943258	2 K982116	3 K013814	4 K063271	5	6
7	8	9	10	11	12

Data Included in Submission
☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
79FRO		☐ Class I ☐ Class II
Classification Panel: Genreal and Plastic Surgery Devices		☐ Class III ☒ Unclassified

Indications *(from labeling)*

For over-the-counter use: Minor abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, may be used for the management of: wounds as an effective barrier to bacterial penetration to help reduce infection; partial thickness burns; diabetic foot ulcers, leg ulcers and pressure ulcers/sores (partial and full thickness); surgical wounds left to heal by secondary intent; traumatic wounds; wounds that are prone to bleeding such as wounds that have mechanically or surgically debrided; oncology wounds with exudate; management of painful wounds.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)	
Division Name *(if applicable)* (b)(4)		Phone Number *(including area code)* (b)(4)	
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)	
City (b)	State / Province (b)(4)	ZIP/Postal Code (b)(4)	Country (b)
Contact Name (b)(6)	Contact Title Quality Management	Contact E-mail Address (b)(4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

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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.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

ConvaTec
A Bristol-Myers Squibb Company

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 over-the-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) (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

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?		X
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?		X

[A]A 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

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.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CONVATEC
200 HEADQUARTERS PARK DRIVE
SKILLMAN NJ 08558
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
136121983

2. CONTACT NAME
Marilyn Konicky
2.1 E-MAIL ADDRESS
marilyn.konicky@bms.com
2.2 TELEPHONE NUMBER (include Area code)
908-904-2541
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
908-904-2235

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application 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
[ ] 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

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA.
[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 THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support 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

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
16-Nov-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 2 - CDRH Premarket Review Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
ConvaTec	2243969		
Division Name *(if applicable)*	Phone Number *(including area code)*		
division of E.R. Squibb & Sons, L.L.C.	(908) 904-2541		
Street Address	FAX Number *(including area code)*		
200 Headquarters Park Drive	(908) 904-2235		
City	State / Province	ZIP/Postal Code	Country
Skillman	New Jersey	08558	USA
Contact Name			
Marilyn Konicky			
Contact Title	Contact E-mail Address		
Associate Director, US and International Regulatory Affairs	marilyn.konicky@bms.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

FORM FDA 3514 (9/07)

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

MS

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)*
- ☐ 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
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ 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
- ☐ 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
- ☐ Other Reason *(specify)*:

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

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NAC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
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2	K982116	2	AQUACEL Hydrofiber Wound Dressing	2	ConvaTec, div. of E.R. Squibb & Sons, LLC
3	K063271	3	AQUACEL & AQUACEL Ag Wound Dressings (bundled 510(k)	3	ConvaTec, div. of E.R. Squibb & Sons, LLC
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
AQUACEL Wound dressing; Dressing, Wound, Hydrophilic, Class I

	Trade or Proprietary or Model Name for This Device		Model Number
1	AQUACEL Wound Dressing	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K943258	2 K982116	3 K063271	4	5	6
7	8	9	10	11	12

Data Included in Submission
☐ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: NAC
C.F.R. Section *(if applicable)*:
Device Class: ☒ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel: Genreal and Plastic Surgery Devices

Indications *(from labeling)*

For over-the-counter use: Minor abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, may be used for the management of: leg ulcers, pressure ulecer and diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological); second degree burns; management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding suach as wounds that have ben mechanically or surgically debrided, donor sites and traumatic wounds; management of painful wounds.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)
Division Name *(if applicable)* (b)(4)		Phone Number *(including area code)* (b)(4)
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)
City (b)(4)	State / Province (b)(4)	ZIP/Postal Code (b)(4) / Country (b)(4)
Contact Name (b)(6)	Contact Title (b)(4)	Contact E-mail Address (b)(4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

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.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

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VS9

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name ConvaTec	Establishment Registration Number *(if known)* 2243969		
Division Name *(if applicable)* 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 Code 08558	Country USA
Contact Name Marilyn Konicky			
Contact Title Associate Director, US and International Regulatory Affairs	Contact E-mail Address marilyn.konicky@bms.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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PSC Graphics (301) 443-2454 EF

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)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ 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
- ☐ 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
- ☐ Other Reason *(specify)*:

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 Hydrofiber Wound Dressing

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2	NAC	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K943258	1	ConvaTec Hydrocolloid Wound Dressing	1	ConvaTec, div. of E.R. Squibb & Sons, LLC
2	K982116	2	AQUACEL Hydrofiber Wound Dressing	2	ConvaTec, div. of E.R. Squibb & Sons, LLC
3	K013814	3	Absorbent Antimicrobial Wound Dressing	3	ConvaTec, div. of E.R. Squibb & Sons, LLC
4	K063271	4	AQUACEL & AQUACEL Ag Wound Dressings (bundled 510(k)	4	ConvaTec, div. of E.R. Squibb & Sons, LLC
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Absorbent Antimicrobial Wound Dressing; AQUACEL Ag; Wound Dressing; Dressing, Wound, Drug; Unclassified
AQUACEL Wound dressing; Dressing, Wound, Hydrophilic, Class I

	Trade or Proprietary or Model Name for This Device		Model Number
1	AQUACEL Ag with Hydrofiber Silver Impregnated Antimicrobial Dressing	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K943258	2 K982116	3 K013814	4 K063271	5	6
7	8	9	10	11	12

Data Included in Submission
☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: 79FRO
C.F.R. Section *(if applicable)*:
Classification Panel: Genreal and Plastic Surgery Devices

Device Class
☐ Class I ☐ Class II
☐ Class III ☒ Unclassified

Indications *(from labeling)*

For over-the-counter use: Minor abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, may be used for the management of: wounds as an effective barrier to bacterial penetration to help reduce infection; partial thickness burns; diabetic foot ulcers, leg ulcers and pressure ulcers/sores (partial and full thickness); surgical wounds left to heal by secondary intent; traumatic wounds; wounds that are prone to bleeding such as wounds that have mechanically or surgically debrided; oncology wounds with exudate; management of painful wounds.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)	
Division Name *(if applicable)* (b)(4)		Phone Number *(including area code)* (b)(4)	
Street Address (b)(4)		FAX Number *(including area code)* (b)(4)	
City (b)( )	State / Province (b)(4)	ZIP/Postal Code (b)(4)	Country (b)(4)
Contact Name (b)(6)	Contact Title (b)(4)	Contact E-mail Address (b)(4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

SECTION I	UTILIZATION OF STANDARDS				
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Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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ConvaTec
A Bristol-Myers Squibb Company

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 over-the-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) (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?		X
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?		X

[A]A 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

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

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.

(b) (6)

[redacted]al Regulatory Affairs

February 8, 2008
Date

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.

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SECTION 8: FINANCIAL CERTIFICATION STATEMENT

Please see attached Form FDA 3454.

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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 mark the applicable checkbox.

☑ (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) [redacted]

☐ (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	TITLE
(b)(6) [redacted]	Vice President, Global Medical Affairs
FIRM/ORGANIZATION	
ConvaTec, A Division of E.R. Squibb & Sons, L.L.C.	
SIGNA (b)(6) [redacted]	DATE Jan. 25th 2008

Paperwork Reduction Act Statement

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 number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (4/06) PSC Graphics (301) 443-1090 EF

Form FDA 3454 Financial Certification (Continued)

Study Name (b)(4) [redacted]

Study No.: (b)(4) [redacted] (b) [redacted]

Investigator List:

(b)(6) [redacted]

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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 incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- 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 this format under K943258, K982116, or K063271
[2]Indication 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 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**[1]
- **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 sites**[1]
- 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.**

[1]Clarified / 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).

Table of Similarities and Differences
AQUACEL® Hydrofiber® Wound Dressing

Parameter	AQUACEL® (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	Similarities	Differences
Intended Use	External Wound Dressing - absorbs wound exudate - protects wounds - management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - management of painful wounds - provides a moist wound healing environment	Same dressing composition and design. Same basic intended use (management of wounds by absorption of exudate, protection, management of pain, provision of moist wound healing).	There is no difference in the intended use.
Indications for Use	Over-the-Counter Use - abrasions - 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) burns - traumatic or surgical wounds 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 vascular)[1]** - **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	Over-the-Counter Use - abrasions - lacerations - 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-IV) and diabetic ulcers - surgical wounds (post-operative, donor sites, dermatological) - partial thickness (second degree) burns - 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 - management of painful wounds	Both dressings have essentially the same indications for use with the exception of the proposed (bold) highlighted clarification and definition of the indications.	AQUACEL® Dressings are currently indicated for use on **"surgical or traumatic wounds ... left to heal by secondary intent"** and **"surgical wounds (post-operative, donor sites and dermatological)."** The difference is intended to further clarify and define these already cleared indications by amending the text to include, **"such as dehisced 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)."** This is supported by the Hydrofiber® technology in AQUACEL® dressing forming a soft gel, which conforms to the wound, protects 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 aids in removing dead necrotic material from the wound without damaging newly formed tissue. Clinical studies (detailed elsewhere in this application) support the use of the Hydrofiber® technology in AQUACEL® Dressings for the management of surgical 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 intended to simplify and clarify the Indications for Use statement.
Components	Non-woven sodium carboxy-methylcellulose.	Non-woven sodium carboxy-methylcellulose.	Same	No differences

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

Table of Similarities and Differences
AQUACEL® Hydrofiber® Wound Dressing

Parameter	AQUACEL® (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	Similarities	Differences
Mode of Action	The dressing absorbs wound fluid and creates a soft conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.	The dressing absorbs wound fluid and creates a soft conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.	Same	No differences
Characteristics	Sterile Absorbs exudates or blood Forms a soft conformable gel	Sterile Absorbs exudates or blood Forms a soft conformable gel	Same	No differences
Changing Frequency	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.	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.	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, clinical study report (b)(4) (b)
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.	Same	No 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 reepithelialized after fourteen days. The dressing is not intended 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 insert which is located in Sections 13 and 20 of this submission	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 reepithelialized after fourteen days. The dressing is not intended for use as a surgical sponge.	Same	No Differences

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

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
Intended Use	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	Same	No Differences

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

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
Indications for Use	Over-the-Counter Use - abrasions - 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**[1] - **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 of surgically debrided **and donor sites**[1] - oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma - management of painful wounds	Over-the-Counter Use - abrasions - 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) burns - 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	Over-the-Counter Use - abrasions - lacerations - minor cuts - minor scalds and burns Under the supervision of a Health Care Professional, AQUACEL® Ag may be used for the management of: - 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/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® 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, 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 (proposed) is indicated for use in the management of infected wounds and 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 (e.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.

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

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
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 (autolytic 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 unnecessary 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 environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL ® Ag dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed.	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 Forms a 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.

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

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
Changing Frequency	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 AQUACEL® 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) (b)(4)
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

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

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 reepithelialized 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 or impetigo. 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 insert which is located in Sections 13 and 20 of this submission	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 reepithelialized 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 or impetigo.	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 reepithelialized 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 or impetigo.	Same	No differences

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

Summary of Performance Testing

(b)(4)

[redacted]

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(b)(4) Testing

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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.

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 incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]

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

(b)(4) [redacted]

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.

[1]Clarified / New Indication, not previously included in this format under K943258, K982116 or K063271
[2]Indication 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 infection[1]:**

- Surgical wounds 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 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

(b)(4)
[redacted]

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.

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

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Table of Similarities and Differences
AQUACEL® Hydrofiber® Wound Dressing

Parameter	AQUACEL® (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	Similarities	Differences
Intended Use	External Wound Dressing - absorbs wound exudate - protects wounds - management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - management of painful wounds - provides a moist wound healing environment	Same dressing composition and design. Same basic intended use (management of wounds by absorption of exudate, protection, management of pain, provision of moist wound healing).	There is no difference in the intended use.
Indications for Use	Over-the-Counter Use - abrasions - 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) burns - traumatic or surgical wounds 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 vascular)**[1] - **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	Over-the-Counter Use - abrasions - lacerations - 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-IV) and diabetic ulcers - surgical wounds (post-operative, donor sites, dermatological) - partial thickness (second degree) burns - 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 - management of painful wounds	Both dressings have essentially the same indications for use with the exception of the proposed (bold) highlighted clarification and definition of the indications.	AQUACEL® Dressings are currently indicated for use on **"surgical or traumatic wounds ... left to heal by secondary intent"** and **"surgical wounds (post-operative, donor sites and dermatological)."** The difference is intended to further clarify and define these already cleared indications by amending the text to include, **"such as dehisced 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)."** This is supported by the Hydrofiber® technology in AQUACEL® dressing forming a soft gel, which conforms to the wound, protects 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 aids in removing dead necrotic material from the wound without damaging newly formed tissue. Clinical studies (detailed elsewhere in this application) support the use of the Hydrofiber® technology in AQUACEL® Dressings for the management of surgical 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 intended to simplify and clarify the Indications for Use statement.
Components	Non-woven sodium carboxy-methylcellulose.	Non-woven sodium carboxy-methylcellulose.	Same	No differences

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

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Table of Similarities and Differences
AQUACEL® Hydrofiber® Wound Dressing

Parameter	AQUACEL® (proposed)	AQUACEL® (predicate) K943258/K982116/K063271	Similarities	Differences
Mode of Action	The dressing absorbs wound fluid and creates a soft conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.	The dressing absorbs wound fluid and creates a soft conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement), without damaging newly formed tissue.	Same	No differences
Characteristics	Sterile Absorbs exudates or blood Forms a soft conformable gel	Sterile Absorbs exudates or blood Forms a soft conformable gel	Same	No differences
Changing Frequency	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.	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.	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)
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.	Same	No 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 reepithelialized after fourteen days. The dressing is not intended 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 insert which is located in Sections 13 and 20 of this submission.	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 reepithelialized after fourteen days. The dressing is not intended for use as a surgical sponge.	Same	No Differences

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

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
Intended Use	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	External Wound Dressing - absorbs wound exudate - protects wounds - for the management of painful wounds - provides a moist wound healing environment	Same	No Differences

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

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
Indications for Use	Over-the-Counter Use - abrasions - 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[1]** - **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 of surgically debrided **and donor sites[1]** - oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma - management of painful wounds	Over-the-Counter Use - abrasions - 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) burns - 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	Over-the-Counter Use - abrasions - lacerations - minor cuts - minor scalds and burns Under the supervision of a Health Care Professional, AQUACEL® Ag may be used for the management of: - 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/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® 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, 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 (proposed) is indicated for use in the management of infected wounds and 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 (e.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.

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

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
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 (autolytic 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 unnecessary 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 environment to support the healing process.. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL ® Ag dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed.	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 Forms a 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.

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

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
Changing Frequency	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 AQUACEL® 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) (b)(4) (b)(4) Testing
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

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

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 reepithelialized 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 or impetigo. 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 insert which is located in Sections 13 and 20 of this submission	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 reepithelialized 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 or impetigo.	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 reepithelialized 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 or impetigo.	Same	No differences

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

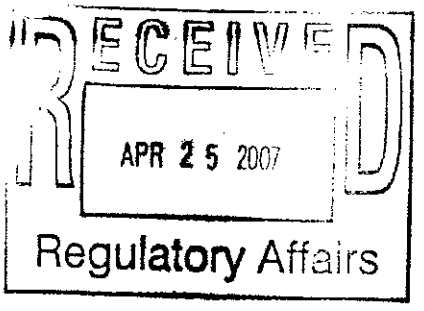
DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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.

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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Peter D Rumm

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

Enclosure

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2002

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.

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.

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 in vitro 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,

for Mark N. Melkerson

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

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).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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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,

for 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

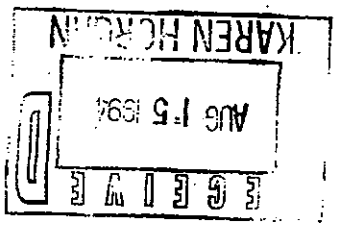
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 4 1994

Food and Drug Administration
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



Re: K943258
ConvaTec Hyrocolloid Wound Dressing
Regulatory Class: Unclassified
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:

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).

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.

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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. An 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

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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.

(b)(4) Draft Document

(b)(4) Draft Document

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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.

SECTION 15: BIOCOMPATIBILITY

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

(b)(4) [redacted]

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

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SECTION 16: SOFTWARE

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

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.

SECTION 18: PERFORMANCE DATA – BENCH

Performance data has been submitted for both products covered under this bundled 510(k). (b)(4)

(b)(4)

SECTION 19: PERFORMANCE DATA - ANIMAL

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

SECTION 20: PERFORMANCE TESTING - CLINICAL

(b)(4)

[redacted]

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Current Package Insert

STERILE

AQUACEL®

Hydrofiber® Wound Dressing

INSTRUCTIONS FOR USE

ConvaTec

Do Not Reuse

misc 2026

STERILE R Gamma Sterilized

misc 2017

REF Order Number

misc 2125

Attention: See Instructions for Use

MISC 2045

LOT Lot

MISC 2063

Expiration Date

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 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)
- 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.

- 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:
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Made in UK

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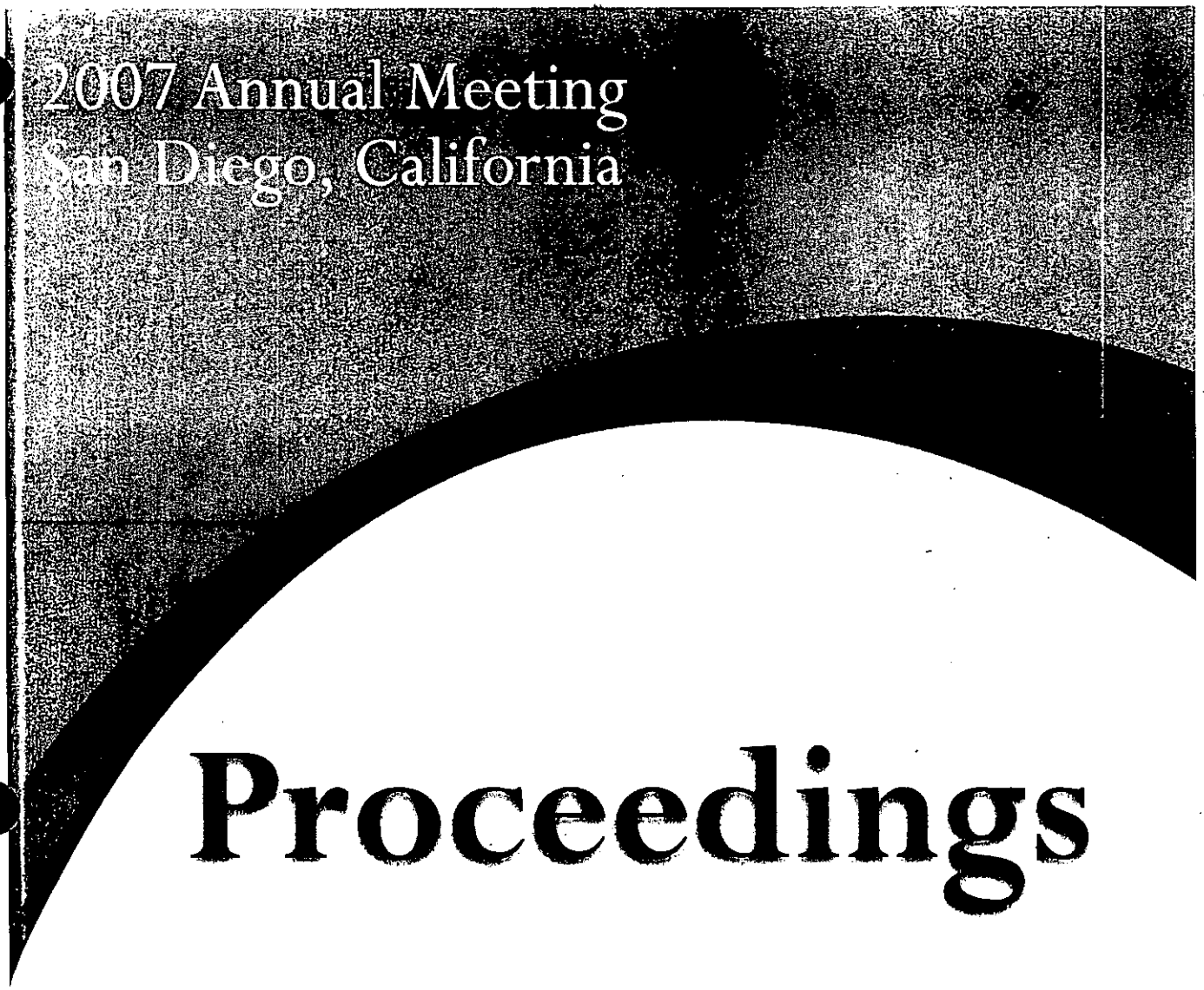

Proceedings

Meeting Dates
February 14-18, 2007

Exhibit Dates
February 14-16, 2007

AAOS
American Academy of Orthopaedic Surgeons

femoral stem and Ring Loc acetabular shell were assessed at a minimum of 60 (mean of 89.5 ± 9.6) months for acetabular polyethylene 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 femoral offset using SPSS12.0 (Chicago, IL). 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 ± 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. P036

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

Alister Hart, FRCS, London, United Kingdom (*)
Pranai Buddhev, BSc (*)
Payam Tarassoli, BSc (*)
Jonathan Powell, PhD (*)
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, clearance, 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 inclination 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 cobalt 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/L). This finding was statistically significant, with a Pearson correlation coefficient of 0.46 (95% CI 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. P038

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 (THR) 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.

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 rarely 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. P040

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 hydroxyapatite-coated smooth uncemented 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 follow-up 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. P041

◆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 JIA 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 4 cases 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 osseointegrated stems in 74 hips. There was stable subsidence of 1 CADCAM stem not requiring revision, and subsidence of 2 CADCAM 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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PAPERS, POSTERS & SCIENTIFIC EXHIBITS AR HIP

• The FDA has not cleared the drug and/or medical device for the use described in this presentation (i.e. the drug or medical device is being discussed for an off label use). For full information, refer to package insert.

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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.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616; Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
ConvaTec, a Division of E.R. Squibb & Sons, L.L.C.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
February 8, 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
200 Headquarters Park Drive
Skillman, NJ 08558

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 908-904-2500
(Fax) 908-904-2235

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Dressing, Wound, Hydrophilic, Class I, AQUACEL® Dressing

Dressing, Wound, Drug, Unclassified, AQUACEL® Ag Dressing

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
N/A

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
N/A

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Marilyn Konicky

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Marilyn Konicky
(Title) Associate Director, US and International Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
200 Headquarters Park Drive
Skillman, NJ 08558

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 908-904-2541
(Fax) 908-904-2235

15. DATE OF CERTIFICATION
02/08/2008

FDA-3674 (1/08) (FRONT)
PSC Graphics: (301) 443-1090 EF

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name David Krause, PhD

Subject: 510(k) Number K080383

To: The Record

Please list CTS decision code SE

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

☐ Hold (Additional Information or Telephone Hold).

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
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*		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
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?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number Unclassified **Class*** **Product Code** FRO

(*If unclassified, see 510(k) Staff)

Additional Product Codes: NAC

Review: David Krause (Branch Chief) PRSB (Branch Code) ~~April 30, 2008~~ May 2, 2008 (Date)

Final Review: (Division Director) for Nan Shly (Date)

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):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			✓
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			✓
3. Does this device type require a PMA by regulation? (Please see management.)			✓
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			✓
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)		NA	
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:		✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			✓

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

OK [signature] DE 5/2/08

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		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
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)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
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,

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:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This issue is not applicable to this device.

XI. Performance Testing – Bench

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:

(b)(4)

[redacted]

(b)(4) Testing

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	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?			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?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%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

March 26, 2008: I sent the sponsor representative, Ms. Konicky, an email asking her to modify the (b)(4) (b)(4). Sponsor responded on April 17, 2008 with

April 17, 2008: Requested (b)(4). Sponsor responded with (b)(4) on April 17, 2008.

April 18, 2008: Requested a few additional (b)(4). These were provided on April 21, 2008.

May 1, 2008: Requested an additional revision to (b)(4).

All issues were resolved.

XVII. Recommendation

Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: FRO, Wound dressing with a drug

Daniel Krause
Expert Biologist & Branch Chief

May 2, 2008
Date

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) [redacted] (b)(4) [redacted]

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(b)(4) [redacted]. The reviewer agrees with this statement.

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

Subject Device: Aquacel Hydrofiber Dressing (K982116) and Aquacel Hydrofiber AG (K013814)

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***

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***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-cutaneous 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:

(b)(4)

[redacted] for the subject device is acceptable and is considered the same as the predicate device.

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

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, non-woven 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 non-viable 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, non-adherent 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.

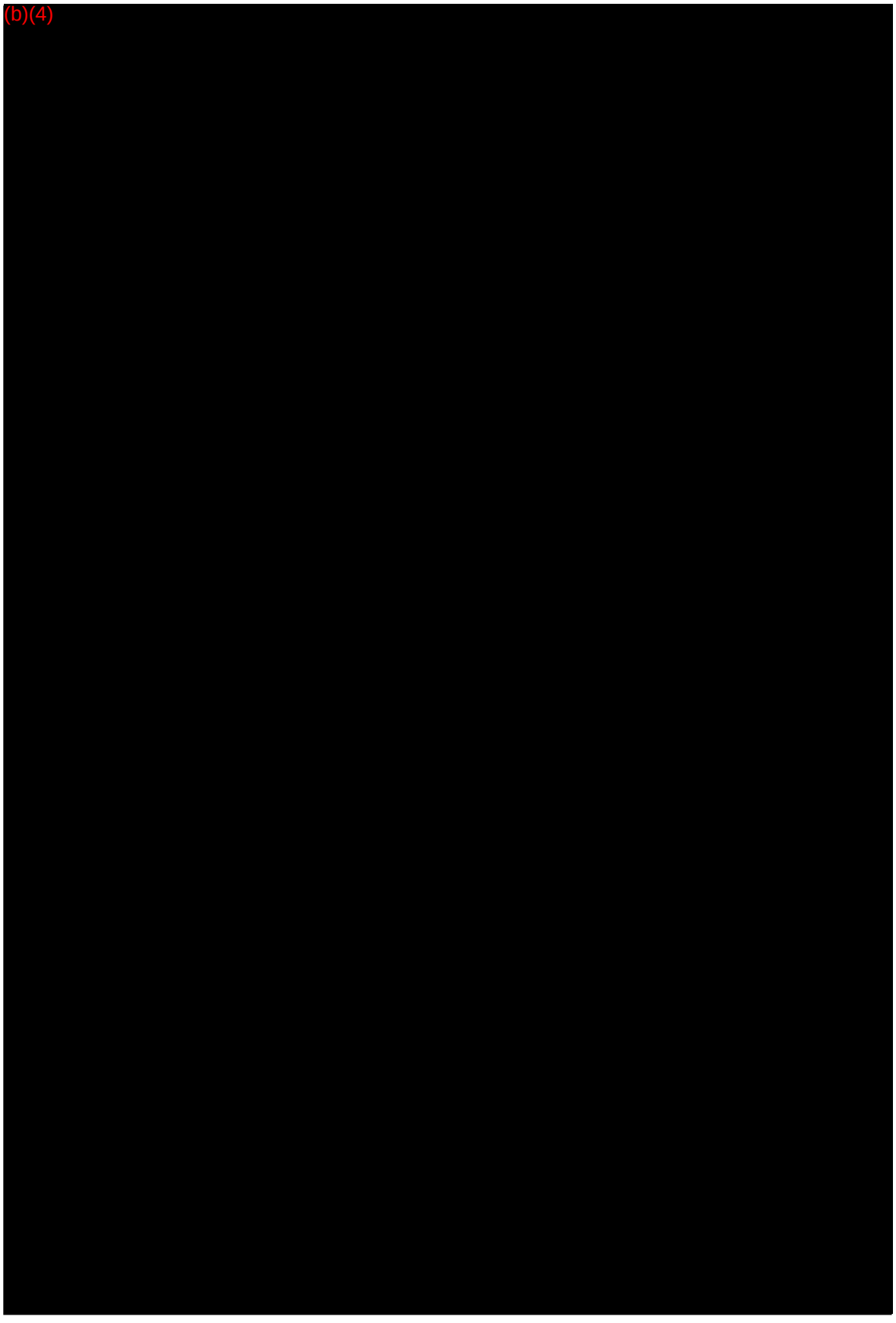
The device compositions are different, in that, Aquacel is a hydrocolloid made of sodium carboxy methylcellulose (Aquacel AG additionally contains 1.2% ionic silver) and Mepitel is made of silicone and a polyamide tricot net. Both devices are supplied sterile and can be kept in place for several days. 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)**

(b)(4)

[redacted]

(b)(4)



17

(b)(4)

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"

Sterilization method (b)(4)
Validation: (b)(4)
Packaging: The dressing is packaged in a (b)(4) (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**

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6. Labeling claims

ConvaTec submitted six claims for advertising purposes. (b)(4)

[redacted]

(b)(4)

[redacted]

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

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

7. **Has sponsor provided all administrative requirements?**

- 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)**

(b)(4)

[redacted]

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)

[redacted]

20

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(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

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.

Suzanne Ballli 04/12/07

Name Date

Plastic and Reconstructive Surgery Devices Branch

I concur David Krause 4/13/07

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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:
Capt. Stephen Rhodes, Branch Chief PRSB
David Krause, PhD, Reviewer
Sam Arepalli, PhD, Reviewer
Suzanne Malli, BA, BSN, Reviewer
Jiyoung Dang, PhD, Reviewer
Peter Rumm, M.D., Deputy Division Director, DGRND
Thomas Knott, Office of Compliance, GSDB

ConvaTec Attendees:
(b)(6), VP, Reg Aff
(b)(6), Dir, Reg
(b)(6), Director, Anti-Infectives
(b)(6), Legal Counsel
(b)(6), Assoc Director, Reg

Via teleconference:
(b)(6), Chief Scientific Officer

Areas of Concurrence:

(b)(4)

Next Steps:

- Sponsor will submit a response to the Additional Information request

Suzanne Malli, BA, BSN, Reviewer, PRSB 3/27/07

Capt. Stephen Rhodes, Branch Chief, PRSB 3/29/07

DK 4/13/07

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Krause, David

From: (b)(4)
Sent: Thursday, May 01, 2008 4:35 PM
To: 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

ConvaTec
A Bristol-Myers Squibb Company

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) [redacted]

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 marilyn.konicky@bms.com.

Sincerely,

(b)(6) [redacted]

Associate Director
US and International Regulatory Affairs

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 incisions**[1]
- **Surgical wounds that heal by primary intent, such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- 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
[2]Indication 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)

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 incisions**[1]
- **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 sites**[1]
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- **Infected Wounds**[1]

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

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

Krause, David

From: (b)(4) [redacted]
Sent: Monday, April 21, 2008 4:30 PM
To: Krause, David
Cc: (b)(6) [redacted]
Subject: Re: Additional Modifications - K080383 - AQUACEL and AQUACEL Ag Dressings
Attachments: (b)(4) [redacted]

Dear Dr. Krause,

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

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,
>
> (b)(4) [redacted]
>
> David

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 over-the-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.

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 non-adherent, 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 control[1] ($p<0.001$). 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 wound[3]. 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.

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: 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

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 non-adherent, 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™

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 control[1] ($p<0.001$). 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 wound[3]. 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.

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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
To: 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: (b)(4)

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: (b)(4)
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

AQUACEL® Hydrofiber® Wound Dressing
(b)(4)

In response to your e-mail of March 26, 2008, the following revisions to the (b)(4) 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 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 (908) 904-2541 or via e-mail at marilyn.konicky@bms.com.

Best regards,
(b) (6)
Associate Director, Regulatory Affairs

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. (b)

(b)(4)

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

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

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

(b)(4) Draft Document

Krause, David

From: (b)(4)
Sent: Thursday, April 17, 2008 2:42 PM
To: 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) with the changes discussed.

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

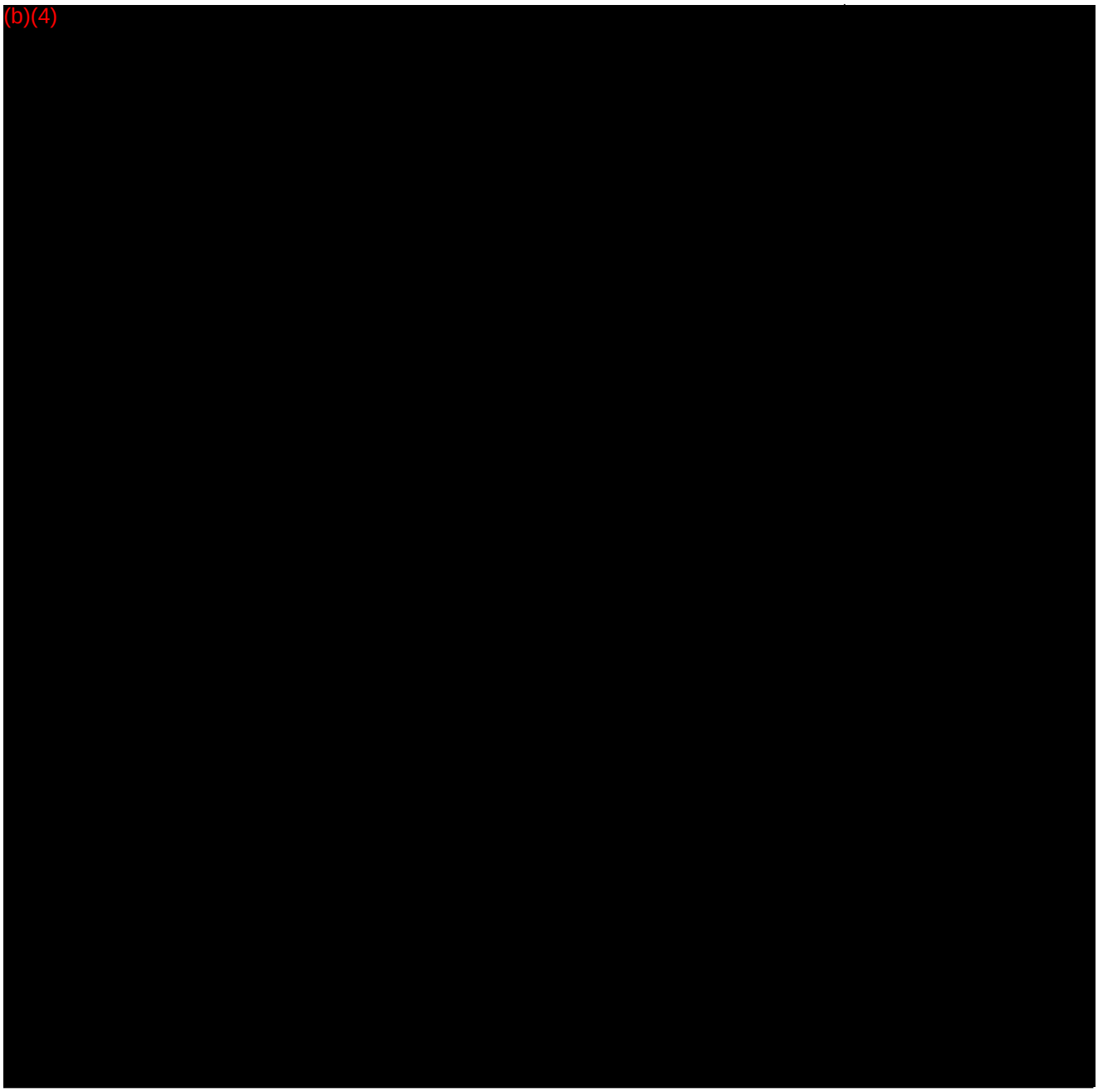
Dear Dr. Krause,

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:

(b)(4)

(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 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 Ag Wound Dressings and have a few observations.(b)(4)

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

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

Krause, 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
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)

(b)(4) [redacted]

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 (908) 904-2541 or via e-mail at marilyn.konicky@bms.com.

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

(b)(4) [redacted]

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

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

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.

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

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- Provides an antimicrobial barrier to the incision site.

(b)(4) Draft Document

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