K043296

510 (k) Summary

1. **Date Prepared:** November 15, 2004

2. **Submitter**

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Submission Correspondent:
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Covalon Technologies Inc.
14510 Kandi Court
Largo, Florida 33774
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4. **Proprietary Name:** ColActive Ag™ Collagen with Silver, Antimicrobial Dressing

Common Name: Wound Dressing

5. **Regulatory Class:** MPG

6. **Statement of Substantial Equivalence:**

ColActive Ag™ Collagen with Silver, Antimicrobial Dressings are substantially equivalent in materials of construction and intended use and identical in function to FIBRACOL PLUS Collagen Wound Dressing with Alginate manufactured by Johnson & Johnson Medical, Vitaphore Silver Foam Wound Dressing manufactured by Vitaphore Corporation and Acticoat Silver Coated Dressing manufactured by Westaim Biomedical, Inc.

7. **Indications For Use:**

ColActive Ag™ Collagen with Silver, Antimicrobial Dressing is indicated for the management of full and partial thickness wounds including:

- Pressure ulcers
- Diabetic ulcers
- Ulcers caused by mixed vascular etiologies
- Venous ulcers
- First and Second degree burns
- Donor and graft sites
- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

8. Description:

ColActive Ag™ Collagen with Silver, Antimicrobial Dressing is an advanced wound care dressing composed of collagen, sodium alginate and silver chloride provided in a sterile sheet or rope form. ColActive Ag™ Collagen with Silver, Antimicrobial Dressings are pliable, absorbent dressings that absorb moisture such as wound fluid forming a gel, thus maintaining a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. The dressings act as an effective barrier to bacterial and fungal penetration. The silver content is intended to prevent colonization of the dressing. The dressings can be cut to fit specific wounds and are able to be layered for the management of deep wounds."

9. Biocompatibility:

ColActive Ag™ Collagen with Silver, Antimicrobial Dressings have been demonstrated to be safe wound dressings. To support the biocompatibility of these products, safety tests were conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices.

When all test results from tests conducted on ColActive Ag™ Collagen with Silver, Antimicrobial Dressings are taken into consideration as a whole, ColActive Ag™ Collagen with Silver, Antimicrobial Dressings have been demonstrated to be safe topical wound dressings in accordance with ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 - 2005

Mr. Paul L. Guilbaud
Vice President and Director of Wound and Tissue Repair
Covalon Technologies Incorporated
14510 Kandi Court
Largo, Florida 33774

Re: K043296
Trade/Device Name: ColActive Ag™ Collagen with Silver, Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 20, 2005
Received: May 23, 2005

Dear Mr. Guilbaud:

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 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510 (k) Number: k 043296
Covalon Technologies, Inc.

Device Name: ColActive Ag™ Collagen with Silver, Antimicrobial Dressing

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- Venous ulcers
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- Donor and graft sites
- Abrasions & lacerations
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(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 K043296