K052696

510 (k) Notification
CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing
Covalon Technologies Ltd.

FEB 3 2006

pg 1/4

510 (k) Summary

OWNERS NAME:	COVALON TECHNOLOGIES LTD.
ADDRESS :	405 BRITANNIA ROAD EAST, SUITE 106 MISSISSAUGA, ONTARIO, CANADA L4Z 3E6
CONTACT PERSON:	ROBERT B. MILLER MD. FRCS(C), FACS DIRECTOR OF CLINICAL AND REGULATORY AFFAIRS
PHONE :	(905) 568-8400
FAX:	(905) 568-5200
DATE OF PREPARATION:	SEPTEMBER 25, 2005
NAME OF DEVICE:	**CovaClearAg™** COLLAGEN WITH SILVER, ANTIMICROBIAL GEL SHEET DRESSING
COMMON NAME:	WOUND DRESSING
CLASSIFICATION NAME:	WOUND DRESSING (21 CFR 807.87 PRODUCT CODE FRO)
SUBSTANTIAL EQUIVALENCE:	ColActiveAg™ Collagen with Silver Antimicrobial Wound Dressing (k043296) SilvaSorb® Silver Antimicrobial Dressing (k002599)

DEVICE DESCRIPTION: CovaClearAg™ Collagen with Silver, Antimicrobial, Gel Sheet Dressing is an advanced wound care dressing composed of collagen and silver lactate provided in a sterile sheet. CovaClearAg™ Collagen with Silver, Antimicrobial Dressings are pliable, hydrated collagen sheets that maintain a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. Because of its significant water content (77.5%), the dressing provides hydration to the wound surface.

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 can be layered for the management of deep wounds.

INTENDED USE: CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet 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, Donor and Graft sites, Abrasions and lacerations, Traumatic wounds healing by secondary intention, Dehisced surgical wounds, First & Second degree burns.

Precautions:

If sensitivity to the product develops, discontinue use. CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing may be used under compression therapy under the supervision of a health care professional.

Contraindications:

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressings should not be used on patients with a known allergy or sensitivity to porcine collagen, to silver or on third degree burns.

K052696

510 (k) Notification
CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing
Covalon Technologies Ltd.

pg 3/4

Warning: This device, when used in preclinical animal testing (in vitro testing) has demonstrated a hemolytic activity above the normal levels. This device is intended for topical use only and should not be used in deeper wounds beyond the Indications for Use statement.

(Amendment fax dated January 24, 2006 – DXV)

Technological Characteristics of Device:

COMPARATIVE TABLE

CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet Dressing
ColActive Ag™ Collagen with Silver, Antimicrobial Dressing
SilvaSorb® Silver Antimicrobial Wound Dressing

Product Name	CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing	ColActiveAg™ Collagen With Silver Antimicrobial Dressing	SilvaSorb®, Silver Antimicrobial Dressing
Manufacturer	Covalon Technologies Ltd.	Covalon Technologies Ltd.	AcryMed, Inc
Regulatory status	Subject of this 510(k)	K043296	K002599
Materials of Construction	Collagen Silver Lactate Silver Chloride	Collagen ,Alginate Silver Lactate Silver Chloride	Polyacrylate, Silver Chloride
Sterility	Sterile	Sterile	Sterile
Comparable Sizes	Yes	Yes	Yes
Biocompatibility Testing	Yes	Yes	Yes
Intended Use	Pressure, venous, diabetic, Vascular ulcers, 1st & 2nd degree burns, various surgical & traumatic wounds	Pressure, venous, diabetic, vascular ulcers, 1st & 2nd degree burns, various surgical & traumatic wounds	Pressure, venous, diabetic, vascular ulcers, 1st & 2nd degree burns, various surgical & traumatic wounds
Antimicrobial Effect	Yes	Yes	Yes

Safety & Efficacy Evaluation

Biocompatibility Testing:

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing has been tested for biocompatibility as outlined in the General Program Memorandum - #G95-1, Office of Device Evaluation entitled "Use of International Standard ISO – 10993 – "Biological Evaluations of Medical Devices Part 1: Evaluation and Testing". These were performed on our finished packaged device that has undergone a validated sterilization process.

We believe that this position is consistent with that set down in FDA Document 'Draft Guidance for the Preparation of a Pre-market Notification for a Non-Interactive Wound and Burn Dressing', Second Revision – November 26, 1997. **Attachment I** contains a testing schedule of all biocompatibility tests conducted that demonstrate that CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing is biocompatible, along with all test results.

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing is made from the same Gelatin as it's predicate ColActive Ag™. In the 510(k) filing for ColActiveAg™, the FDA was concerned regarding the inactivation of Porcine Parvo Virus (PPV) and Swine Influenza Virus (SIV) in the gelatin manufacturing process or through the sterilization process of the final device. For that 510(k) filing, Covalon conducted a review of the manufacturing process of the raw material as well as the sterilization process and how it affects the PPV and SIV, and included an extensive literature review to support the inactivation of the two aforementioned viruses. The data provided demonstrated the inactivation of both viruses and consequently the safety of the raw material. **(Attachment XII)**

CONCLUSIONS:

It has been shown that CovaClearAg™ is comparable in composition with the predicate devices and shows substantial equivalence. The Biocompatibility testing shows safety of the product. Results of the Kirby-Bauer testing shows the product functions with respect to its antimicrobial claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Robert B. Miller, M.D., FRCS(C), FACS
Director of Clinical and Regulatory Affairs
Covalon Technologies Ltd.
405 Britannia Road East, Suite 106
Mississauga, Ontario L4Z 3E6
CANADA

Re: K052696
Trade/Device Name: CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 13, 2006
Received: January 17, 2006

Dear Dr. Miller:

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" (21 CFR 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,

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

Enclosure

510 (k) Notification
CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing
Covalon Technologies Ltd.

Indications for Use

510(k) Number: K052696

Device Name: CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet Dressing

Indications for Use: CovaClearAg™ Collagen with Silver, Antimicrobial Gel Sheet

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
- donor and graft sites
- abrasions and lacerations
- traumatic wounds healing by secondary intention
- dehisced surgical wounds
- first and second degree burns

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

510(k) Number K052696