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Premarket Notification (510(k)) Summary

1. Sponsor information

Covalon Technologies Inc.
405 Britannia Road East,
Suite #106
Mississauga, Ontario, Canada
L4Z 3E6

AUG 13 2012

Contact person: Christopher Fredric
Manager, Clinical & Regulatory Affairs

Phone number: 1-905-568-8400 x 261

Fax number 1-905-568-5200

Date of summary: 07 June 2012

2. Device name and classification

Common Name: Wound Dressing, Antimicrobial

Proprietary Name: SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

Device Classification: Antimicrobial Dressing, Unclassified

Classification Panel: General and Plastic Surgery

3. Predicate devices

<u>Manufacturer</u>	<u>Device</u>	<u>510(k) number</u>
3M Health Care	3M™ Tegaderm™ CHG Dressing	K080620
3M Health Care	3M™ Tegaderm™ Transparent Dressing	K973036
Maersk Medical, Ltd.	Arglaes® Film Antimicrobial Barrier Dressing	K990810
Molnlycke Health Care	Mepitac® Soft Silicone Tape	Class I
Ethicon Inc.	BIOPATCH	K003229

4. Indications for use

SurgiClear™ is intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures, and wires.

SurgiClear™ may also be used to cover and secure primary dressing.

K151819
2/2

SurgiClear™ inhibits microbial growth within the dressing and prevents external contamination.

5. Performance testing

SurgiClear™ is composed of a clear polyurethane film coated with a silicone adhesive containing chlorhexidine and silver salts. The following tests were performed on SurgiClear™:

- *In vitro* log reduction
- Biocompatibility studies, including, cytotoxicity, sensitization, irritation, systemic toxicity and sub-chronic toxicity in accordance with ISO 10993
- Porcine wound healing study
- Human repeat insult patch test

6 Substantial equivalence

Performance testing confirmed that SurgiClear™ is substantially equivalent to the predicate devices with regard to materials, intended use and technological characteristics, pursuant to section 510(k).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

AUG 13 2012

Covalon Technologies Incorporated
% Mr. Christopher Fredric
Manager, Clinical and Regulatory Affairs
405 Britannia Road East, Suite 106
Mississauga, Ontario, Canada
L4Z 3E6

Re: K121819

Trade/Device Name: SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with
Chlorhexidine and Silver

Regulation Name: Wound Dressing, Antimicrobial

Regulatory Class: Unclassified

Product Code: FRO

Dated: June 19, 2012

Received: June 21, 2012

Dear Mr. Fredric:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

K121819 26

Indications for Use

510(k) Number: K _____

Device Name: SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K121819