DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 14, 2017

Covalon Technologies, Inc.
Kim Crooks
VP Of Operations
1660 Tech Avenue
Unit 5
Mississsauga, L4W 5S7 CA

Re: K163556
Trade/Device Name: Mediclear PreOp
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: August 17, 2017
Received: August 18, 2017

Dear Kim Crooks:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tara A. Ryan -S

Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163556

Device Name
MediClear™ PreOp

Indications for Use *(Describe)*
MediClear™ PreOp is indicated for use as a pre-operative (incision/insertion) drape that provides continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination.
MediClear™ PreOp can be left on the preoperative incision site for up to 7 days.
MediClear™ PreOp is intended to be used on intact skin and for external use only.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K163556

510(k) Summary

In accordance with 21 CFR 807.92, the following information is provided for Covalon's MediClear PreOp antimicrobial self-adherent silicone film drape for pre-operative skin with chlorhexidine and silver 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued August 12, 2005.

I. Sponsor Information

Contact Address:	Covalon Technologies, Inc. 1660 Tech Avenue, Unit 5 Mississauga, Ontario, Canada L4W 5S7
Contact Person: **Title:**	Kim Crooks VP of Operations
Phone Number:	905-568-8400 x265
Fax Number:	905-568-5200
Date of Summary:	September 07, 2017

II. Device Name and Classification

Device Name:	MediClear™ PreOp
Common Name:	Surgical Drape and Drape Accessories
FDA Panel:	General & Plastic surgery
Product Code:	KKX
Class:	II
Model No(s).:	7000404; 7000630; 7001012

III. Predicate Devices

Manufacturer:	3M Healthcare Company	3M Healthcare Company
Device:	3M™ Steri-Drape™ CHG Antimicrobial Incise Drape	3M™ Ioban™ 2 Antimicrobial Incise Drape
510(k):	K140250	K801550

IV. Reference Devices

Manufacturer:	Covalon Technologies, Inc.	Covalon Technologies, Inc.
Device:	SurgiClear ™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver	IV Clear ™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver
510(k):	K121819	K112549

V. Device Description

MediClear™ PreOp consists of a clear polyurethane film coated with an antimicrobial silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts and is intended to cover and protect skin from the risk of contamination prior to an invasive procedure (i.e. incision or insertion). The chlorhexidine and silver contained in the adhesive provides continuous antimicrobial activity while the polyurethane barrier film acts as a protective patient covering to isolate a procedural site from microbial and other contamination.

MediClear™ PreOp provides an effective physical barrier against external contamination including fluids, bacteria, and yeast. *In vitro* testing* demonstrates that the chlorhexidine and silver incorporated within the silicone adhesive provides a rapid bactericidal and fungicidal effect against microorganisms including *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis*, *Enterococcus faecalis* (VRE), *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Enterobacter cloacae*, *Candida albicans*, and *Candida tropicalis* averaging a 99.9% reduction at 10 minutes and a 99.99% reduction at 30 minutes, and prevents their re-growth for up to 7 days during wear. **In vitro* effectiveness does not predict clinical performance.

MediClear™ PreOp is a breathable, transparent, self-adhesive silicone film that conforms to the contours of the body.

VI. Indications for Use

MediClear™ PreOp is indicated for use as a pre-operative (incision/insertion) drape providing continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination.

MediClear™ PreOp may be left on the pre-operative incision site for up to 7 days.

MediClear™ PreOp is intended to be used on intact skin and for external use only.

VII. Performance Testing

The following tests were conducted to evaluate performance of the subject device*:

-*In vitro* microbial log reduction;
-Real time aging and stability;
-Distribution simulation (journey hazards);
-Biocompatibility including cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogen, and subacute toxicity;
-Operational qualification including visual, functional, and additional criteria;
-Microbial strikethrough;
- Liquid barrier ASTM F1670.

**In vitro* effectiveness does not predict clinical performance.

VIII. Substantial Equivalence

Performance testing, including bench, biocompatibility, shelf life, log-reduction, and human clinical studies, confirms that MediClear™ PreOp is substantially equivalent in that it has similar technological characteristics as its predicate devices, 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape pursuant to section 510(k).

MediClear™ PreOp has an intended use equivalent to its predicates, 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape and aligns with the drape and drape accessory definition per FDA regulation 878.4370 which states that this device is intended to be used as a protective patient covering such as to isolate a site of surgical incision from microbial and other contamination. MediClear™ PreOp is indicated for use as a pre-operative (incision/insertion) drape providing continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination. MediClear™ PreOp and its predicates, 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape are all intended for use as drapes with continuous antimicrobial activity. Both MediClear™ PreOp and its predicates 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape are intended for external use only.

The use of MediClear™ PreOp, a device similar in all technological characteristics to its predicates 3M™ Steri-Drape™ CHG Antimicrobial Incise Drape and 3M™ Ioban™ 2 Antimicrobial Incise Drape raises no new or different issue(s) of safety and effectiveness. Please refer to Table VIII-1 for the comparison between the subject device and the predicate devices.

Table VIII-1 Predicate device comparison table

Device name	***MediClear™ PreOp antimicrobial self-adherent silicone film for preoperative skin with chlorhexidine and silver***	***3M™ Steri-Drape™ CHG Antimicrobial Incise Drape (Predicate #1)***	***3M™ Ioban™ 2 Antimicrobial Incise Drape (Predicate #2)***
Manufacturer	Covalon Technologies,	3M Company	3M Company

	Inc.		
510(k)	Subject device	K140250	K801550
Class	Class II	Class II	Class II
Product code	KKX	KKX	KKX
Classification panel	General and plastic surgery	General and plastic surgery	General and plastic surgery
Common name	Surgical Drape and Drape Accessories	Surgical Drape and Drape Accessories	Surgical Drape and Drape Accessories
Intended Use	MediClear™ PreOp is indicated for use as a pre-operative (incision/insertion) drape providing continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination. MediClear™ PreOp may be left on the pre-operative incision site for up to 7 days. MediClear™ PreOp is intended to be used on intact skin and for external use only.	3M™ Steri-Drape™ is indicated for use as an incise drape with continuous antimicrobial activity. It is intended for external use only.	3M™ Ioban™ is indicated for use as an incise drape with continuous antimicrobial activity. It is intended for external use only.
Used on intact skin or incision site	Used on intact skin	Used on incision site	Used on incision site
General design	MediClear™ PreOp is a clear polyurethane film coated with an antimicrobial silicone adhesive.	3M™ Steri-Drape™ is an antimicrobial impregnated adhesive coated on a breathable film with silicone-coated release liner.	3M™ Ioban™ is an antimicrobial impregnated adhesive coated on a breathable film with silicone-coated release liner.
Active antimicrobial agents	Chlorhexidine diacetate and silver sulfate	Chlorhexidine gluconate (CHG)	Iodine
Packaging	Tyvek Pouch	Film/Tyvek Pouch	Foil Pouch
ASTM F1670 Liquid Barrier Performance	Level 4	Level 4	Level 4
Biocompatible per ISO 10993	Under the conditions of the studies employed, the device is non-cytotoxic, non-irritating, does not induce acute or subacute toxicity and is non-pyrogenic as per the rabbit pyrogen test.	Not cytotoxic, slight irritant, not a potential skin sensitizer	Not cytotoxic, slight irritant, not a potential skin sensitizer
Sold Sterile	Yes	Yes	Yes
Sterilization	Ethylene Oxide (ETO) sterilized,10^{-6} SAL per ISO 11135	ETO sterilized, 10^{-6} SAL per ISO 11135	Gamma sterilized, 10^{-6} SAL per ISO 11137
Single use	Yes	Yes	Yes
Over the Counter	Yes	Yes	Yes

In addition, MediClear™ PreOp, is a device similar in all technological characteristics and performance specifications to the previously FDA cleared reference devices SurgiClear™ (K121819) and IV Clear™ (K112549) with exception of silver salt identity and other minor variations. Please refer to Table VIII-2 for the comparison between the subject device and the reference devices.

Table VIII-2 Reference device comparison table

Device name	***MediClear™ PreOp antimicrobial self-adherent silicone film drape for preoperative skin with chlorhexidine and silver***	***SurgiClear™ antimicrobial clear silicone adhesive dressing with chlorhexidine and silver***	***IV Clear™ antimicrobial clear silicone adhesive dressing with chlorhexidine and silver***
Manufacturer	Covalon Technologies, Inc.	Covalon Technologies, Inc.	Covalon Technologies, Inc.
510(k)	Subject device	K121819	K112549
Class	Class II	Unclassified	Unclassified
Product code	KKX	FRO	FRO
Classification panel	General and plastic surgery	General and plastic surgery	General and plastic surgery
Common name	Surgical Drape and Drape Accessories	Dressing, wound, drug	Dressing, wound, drug
Indications for Use statement	MediClear™ PreOp is indicated for use as a pre-operative (incision/insertion) drape providing continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination. MediClear™ PreOp may be left on the pre-operative incision site for up to 7 days. MediClear™ PreOp is intended to be used on intact skin and for external use only.	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 dressings. SurgiClear™ inhibits microbial growth within the dressing and prevents external contamination.	IV Clear™ is intended to cover and protect insertion sites, and secure devices to skin. Common applications include IV catheters, central venous lines, PICCs, suction catheters, epidural catheters, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices. IV Clear™ inhibits microbial growth within the dressing and prevents external contamination.
Used on intact or breached skin	Used on intact skin	Used on breached skin	Used on insertion site
General design	MediClear™ PreOp is a clear polyurethane film coated with an antimicrobial silicone adhesive.	SurgiClear™ is a clear film which allows the site or the wound to be constantly monitored and assessed. The dressing is self-adhesive and breathable, allowing for good moisture vapor exchange.	The clear film allows continual site observation, and is breathable, allowing moisture vapor exchange.

Active antimicrobial agents	Chlorhexidine diacetate and silver sulfate	Chlorhexidine diacetate and silver acetate	Chlorhexidine diacetate and silver acetate
Dressing construct	MediClear™ PreOp is a clear polyurethane film coated with an antimicrobial silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts.	SurgiClear™ is a clear polyurethane film coated with an antimicrobial silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts.	The dressing consists of a clear polyurethane film coated with a silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts.
Wear time	Up to 7 days	Up to 7 days	Up to 7 days
Transparent	Yes	Yes	Yes
ASTM F1670 Liquid Barrier Performance	Level 4	N/A	N/A
Microbial barrier	Yes	Yes	Yes
Biocompatible per ISO 10993	Under the conditions of the studies employed, the device is non-cytotoxic, non-irritating, does not induce acute or subacute toxicity and is non-pyrogenic as per the rabbit pyrogen test.	Cytotoxic, not a dermal sensitizer, not a dermal sensitizer, no systemic toxicity, no subacute toxicity,	Cytotoxic, not a dermal sensitizer, not a dermal sensitizer, no systemic toxicity, no subacute toxicity,
Sterilization	Ethylene Oxide (ETO)	ETO	ETO
Single use	Yes	Yes	Yes

IX. Non-clinical testing summary

The following non-clinical tests have been conducted to support the safety and efficacy of the subject device:

Test item	Refence standard/test method
7-day Antimicrobial activity	ISO 22196:2010-Plastic-Measurement of Antimicrobial Activity on Plastic Surface
Minimum Effective Concentration (MEC) of antimicrobial activity	ISO 22196:2010-Plastic-Measurement of Antimicrobial Activity on Plastic Surface
Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: *Tests for in vitro Cytotoxicity*
Skin Irritation	ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: *Tests for irritation and skin sensitization*
Guinea Pig Maximization Sensitization	ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: *Tests for irritation and skin sensitization*
Acute Systemic Toxicity	ISO 10993-11:2006 Biological Evaluation of Medical Devices- Part 11: *Tests for systemic toxicity*
Subacute Toxicity Test - 4-week Subcutaneous implantation	ISO 10993-6: 2007 Biological Evaluation of Medical Devices Part 6 *Tests for local effects after implantation* ISO 10993-11:2006 Biological Evaluation of Medical Devices- Part 11: *Tests for systemic toxicity*
Implantation	ISO 10993-6: 2007 Biological Evaluation of Medical Devices Part 6 *Tests for local effects after implantation*
Material-mediated	ISO 10993-11:2006 Biological Evaluation of Medical Devices- Part

pyrogencity	11: *Tests for systemic toxicity* USP 30 <151> Pyrogenicity Test
Liquid barrier	AAMI PB-70-2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities & ASTM F1670/F1670M-08(Reapproved 2014) Standard test method for resistance of material used in protective clothing to penetration by synthetic blood
MVTR	E96/E96M-05 *Standard Test Methods for Moisture Transmission of Materials* EN 13726-2-2002 Test methods for primary wound dressings. Part 2: Moisture Vapour Transmission Rate of Permeable Film Dressings
Real time aging	ICH Q1A Stability Testing of New Drug Substances and Products
EO sterilization	ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices* ANSI/AAMI/ISO 10993-7:2008 Biological Evaluation of Medical Devices Part 7: *Ethylene oxide sterilization residuals*
Distribution simulation (journey hazards)	ISTA Project 2A (2008); Performance Test for Individual Packaged-Products 150 lb. or Less. ASTM D 4169-09; *Performance Testing of Shipping Containers and Systems*
Microbial Strikethrough	In-house

X. Clinical Testing

Clinical testing was not needed for this device.

XI. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.