DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 24, 2015

Covalon Technologies, Inc.
Kim Crooks
VP Of Operations
1660 Tech Avenue, Unit 5
Mississauga, Ontario, Canada
L4W 5S7

Re: K150550
Trade/Device Name: SilverCoat™ Silicone Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter And Accessories
Regulatory Class: Class II
Product Code: EZL
Dated: November 17, 2015
Received: November 19, 2015

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 yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150550

Device Name
SilverCoat™ Silicone Foley Catheter

Indications for Use *(Describe)*
To be used as a urological catheter inserted through the urethra to pass urine from the urinary tract by individuals that are ≥ 30 kg and over 12 years of age. SilverCoat™ Silicone Foley Catheters should not be used on patients with known hypersensitivity or allergy to silver or silver-containing organics or inorganics.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

In accordance with 21 CFR 807.92, the following information is provided for Covalon's SilverCoat™ Silicone Foley Catheter 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

I) Sponsor Information

Contact Address:	Covalon Technologies, Inc. 1660 Tech Avenue, Unit 5 Mississauga, Ontario, Canada L4W 5S7
Contact Person:	Kim Crooks VP of Operations
Phone Number:	1-905-568-8400 x265
Fax Number:	1-905-568-5200
Date of Summary:	17 November 2015

II) Device Name and Classification

Common Name:	Urological Catheter
Proprietary Name:	SilverCoat™ Silicone Foley Catheter
Classification Name:	Urological catheter and accessories
Regulation:	21 CFR 876.5130
Model No(s).:	SCC1205GU, SCC1405GU, SCC1605GU, SCC1630GU, SCC1805GU, SCC1830GU, SCC2005GU, SCC2030GU, SCC2205GU, SCC2230GU, SCC2405GU, SCC2430GU
Device Classification:	Class II
Product Code:	EZL
Classification Panel:	Gastroenterology/Urology

III) Predicate Device

Manufacturer:	Medline Industries, Inc.
Device:	Medline SilverTouch™ Silicone Foley Catheter

510(k) Number: K052168

Indications for Use: To be used as a urological catheter inserted through the urethra to pass urine from urinary tract.

Contraindications: Those individuals with a known sensitivity or allergy to metallic silver or silver containing organics or inorganics are excluded from the use of this device.

IV) Device Description

SilverCoat™ Silicone Foley Catheters are 100% silicone Foley catheters that have a lubricious coating impregnated with silver ions. The silver is retained in the hydrophilic coating through ionic bonding and is covalently bonded to the silicone surface. The coating will not peel, flake or crack. The coating hydrates rapidly becoming slippery (lubricious) and maintains its lubricity for at least seven days. The SilverCoat™ catheter complies with the FDA recognized consensus standard, ASTM F623-99 *Standard Performance Specification for Foley Catheter*. The catheters are comprised of a two-lumen shaft with proximal funnel, inflation valve, and distal retaining balloon. Balloon fill volumes are in millimeters and the shaft size is in French (Fr.) which is indicated on the funnel of each individual catheter. The catheters are supplied in individually packaged, sealed single use pouches and they are sterilized by ethylene oxide. The SilverCoat™ Foley Catheter is a prescription-only device and it is intended to be used in healthcare facility/hospital, home, and ambulatory settings.

V) Indications for Use

To be used as a urological catheter inserted through the urethra to pass urine from the urinary tract by individuals that are ≥ 30kg and over 12 years of age. SilverCoat™ Silicone Foley Catheters should not be used on patients with known hypersensitivity or allergy to silver or silver-containing organics or inorganics.

VI) Performance Testing

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

-Resistance to microbial colonization and zone of inhibition (Kirby-Bauer);
-Real time aging and stability;
-Distribution simulation (journey hazards);
-Biocompatibility including: bacterial mutagenicity (AMES assay), cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, extractables/leachables, toxicological risk assessment (TRA), and biological evaluation (BE);
-Physical properties and functional & dimensional testing per ASTM F623-99 and EN 1616, Annex A/D;
-Silver distribution/content, and silver elution;

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

VII) Substantial Equivalence

Covalon's SilverCoat™ Silicone Foley Catheter has identical technological characteristics and performance specifications as the predicate device, Medline Industries, Inc.'s SilverTouch™ Silicone Foley Catheter (K052168). Both devices are manufactured from 100% silicone, have a lubricious coating impregnated with silver ions, and possess the same design features and indications for use. In conclusion, the subject device is substantially equivalent to the predicate device and nonclinical test data demonstrates that the subject device is safe and effective.