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

March 29, 2017

Avery Dennison Corporation
Ms. Lisa Bartakovics
Director of Global Regulatory Affairs
7100 Lindsay Dr., Bldg. 14
Mentor, Ohio 44060

Re: K163529
Trade/Device Name: Reliatect Post-op Dressing With CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm)
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2017
Received: February 23, 2017

Dear Ms. Bartakovics:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K163529

Device Name
The ReliaTect™ Post-Op Dressing with CHG

Indications for Use *(Describe)*
The ReliaTect™ Post-Op Dressing with CHG is intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures, and wires.

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

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

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.

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510(k) Summary
Avery Dennison Corporation
ReliaTect™ Post-Op Dressing with CHG

1. Submitter Information

Name:	Avery Dennison Corporation
Address:	7100 Lindsay Drive Mentor, Ohio 44060
Telephone Number:	+ 1 (440) 534-6000
Contact Person:	Lisa Bartakovics
Telephone Number:	+1 (312) 206-6159
Email:	Lisa.Bartakovics@averydennison.com

Date Prepared: December 15, 2016

2. Device Name

Trade Name:	ReliaTect™ Post-Op Dressing with CHG
Common Name:	Dressing, Wound, Drug
Classification Name:	Unclassified
Product Code:	FRO

3. Predicate Device(s)

- Predicate Device- Covalon SurgiClear™ K121819
- Reference Device- Avery Dennison Benehold CHG Transparent Film Dressing K113836

4. Device Description

The ReliaTect™ Post-Op Dressing with CHG is a transparent adhesive dressing integrated with Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial activity.

In vitro testing (barrier and log reduction) demonstrates the ReliaTect™ Post-Op Dressing with CHG provides an effective barrier against external contamination including fluids (waterproof) and a variety of gram-positive bacteria, gram-negative bacteria, and yeast within the dressing including: Staphylococcus aureus, Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Enterococcus faecalis (VRE), Escherichia coli, Pseudomonas aeruginosa,

Enterobacter aerogenes, Klebsiella pneumonia, and Candid albicans. Reduction in the colonization or microbial growth on the device has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed.

5. Indications for Use

The ReliaTect™ Post-Op Dressing with CHG is intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures, and wires.

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

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

6. Technological Characteristics and Substantial Equivalence

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the commercially available Covalon SurgiClear™ device (K121819). Bench testing studies, including antimicrobial efficacy, demonstrate the two devices have comparable performance. The Intended Use of the ReliaTect™ is equivalent to the SurgiClear™ device.

7. Performance Testing

Performance testing was completed on various characteristics to ensure product requirements were satisfied as well as for comparison against the predicate product. The acceptance criteria were met for all characteristics and comparison against the predicate demonstrated equivalent performance. Performance tests included:

- Fluid Handling Capacity
- Static Absorption
- Moisture Vapor Transmission Rate
- Peel Adhesion to Polyethylene
- Liner Release
- Antimicrobial Effectiveness
- Transparency
- Peel Adhesion to Sutures

Antimicrobial effectiveness testing performed demonstrates that the presence of CHG within the dressing inhibits microbial growth within the dressing.

8. Animal Study

The ReliaTect™ Post-Op Dressing with CHG was subjected to a wound healing evaluation through a porcine study. The objective of this study was to evaluate the wound healing impact of the Post-Op dressing with an active antimicrobial agent on full thickness incisional wounds in Yucatan miniature swine. Results of the study demonstrate the ReliaTect™ Post-Op Dressing and the predicate device achieved equivalent performance.

9. Conclusion

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the Covalon SurgiClear™ device. Bench and Animal performance testing, including antimicrobial effectiveness, demonstrate the two devices are substantially equivalent for their intended use.