Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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,

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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.

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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.

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K163529 Date Received by DCC: Dec 16, 2016

Lead Reviewer: Charles Durfor

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

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4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format . (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.				X	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.					

(b)(4) Confidential and Proprietary Information

B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.					
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).					
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.					

(b)(4) Confidential and Proprietary Information

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b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.					
c) A list and description of each device for which clearance is requested.					
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).					
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.					
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*					
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).					
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use					
b) Technology, including features, materials, and principles of operation					
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).					
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).					

(b)(4) Confidential and Proprietary Information

[redacted]

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b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D					
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).					
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").					
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.					
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.					

(b)(4) Confidential and Proprietary Information

E. Sterilization

If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					

(b)(4) Confidential and Proprietary Information

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.
Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.

20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.					
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.					
c) Identification of device, and/or accessories, and/or components that are reusable.					
21) If the device, and/or accessory, and/or a component is provided sterile:					

(b)(4) Confidential and Proprietary Information

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a) Sterilization method is stated for each component (including dose for radiation sterilization).	(b)(4) Confidential and Proprietary Information				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).					
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.					
d) Sterility Assurance Level (SAL) is stated.					
e) Submission includes description of packaging.					
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).					
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.					
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	(b)(4) Confidential and Proprietary Information				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.					
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.					
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
(b)(4) Confidential and Proprietary Information — Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	(b)(4) Confidential and Proprietary Information				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)					
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).					

H. Software

Submission states that the device: (one of the below must be checked)					
	Does contain software/firmware				
X	Does not contain software/firmware				
	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Software/firmware information not needed for this device (e.g., surgical suture, condom)				
	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

I. Electrical Safety and EMC

Electrical Safety Submission states that the device: (one of the below must be checked)					
	Does require electrical safety evaluation				
X	Does not require electrical safety evaluation				
	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
	Electrical safety information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
	Does require EMC evaluation				
X	Does not require EMC evaluation				

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Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

J. Performance Data - General

If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.				
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.				(b)(4) Confidential and Proprietary Information
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.				
36) If literature is referenced in the submission, submission includes:				
a) Legible reprints or a summary of each article.				
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.				
37) For each completed animal study, the submission provides the following:				
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.				
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.				
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see 21 CFR 809.10(b)(12))

Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
☒ is not an in vitro diagnostic device.				
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.				

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Charles N. Durfor -S 2016.12.20 10:03:21 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Cynthia Chang -S 2016.12.20 10:31:14 -05'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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
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Indications for Use *(Describe)*
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ReliaTect™ may also be used to cover and secure a primary dressing.

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

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Post-Review Reminders

☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: February 10, 2017

Reviewer: Charles Durfor

Subject: Traditional 510(k)# K163529

Applicant: Avery Dennison Corporation

Device Trade Name: Reliatect Post-op Dressing With CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm)

Contact Name: Lisa Bartakovics

Contact Title: Director Of Global Regulatory Affairs

Correspondent Firm: Avery Dennison Corporation

Phone: (440) 534-6000 **Email:** lisa.bartakovics@averydennison.com

Received Date: December 16, 2016

Due Date: March 16, 2017

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name: Wound Dressing With Drug

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K121819	FRO	Surgiclear Antimicrobial Clear Silicone Adhesive Dressing With Chlorhexidine And Silver	Covalon Technologies, Inc.
K113836	FRO	Benehold Chg Transparent Film Dressing (10x12cm) (8.5x12cm) (6.5x7 Cm)	Avery Dennison Belgie, Bvba

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

[redacted]

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment of use of the device/system includes…	Home, Professional Healthcare Facility	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Device Characteristics		Inadequate Or Marked
Is the device a combination product?	4 - Device Coated/Impregnated/Combined Drug	☐
Is the device/system electrical (battery or wall powered)?	No, the device is not electrical	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Charles N. Durfor -S 2017.02.10 15:44:06 -05'00'
Branch Sign-off	Cynthia Chang -S 2017.02.10 16:44:27 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DSD/PRSB2
WO66 RMG424 HFZ-410
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6438

Premarket Notification 510(k) Review

Date: March 28, 2017

Reviewer: Charles Durfor

Subject: Traditional 510(k)# K163529

Applicant: Avery Dennison Corporation

Device Trade Name: Reliatect Post-op Dressing With CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm)

Contact Name: Lisa Bartakovics

Contact Title: Director of Global Regulatory Affairs

Correspondent Firm: Avery Dennison Corporation

Phone: (440) 534-6000 **Email:** lisa.bartakovics@averydennison.com

Received Date: February 23, 2017

Due Date: March 29, 2017

Pro Code(s): FRO **Class:** Unclassified **Reg #:**

Reg Name: Wound Dressing With Drug

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K121819	FRO	Surgiclear Antimicrobial Clear Silicone Adhesive Dressing With Chlorhexidine And Silver	Covalon Technologies, Inc.
K113836	FRO	Benehold Chg Transparent Film Dressing (10x12cm) (8.5x12cm) (6.5x7 Cm)	Avery Dennison Belgie, Bvba

(b)(4) Confidential and Proprietary Information

[redacted]

Recommendation

I recommend that the Reliatect Post-op Dressing With CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm) is/are Substantially Equivalent (SESE)

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo

Reviewer Recommendation

The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment of use of the device/system includes…	Home, Professional Healthcare Facility	☐
Is the device a combination product?	4 - Device Coated/Impregnated/Combined Drug	☐
Is the device/system electrical (battery or wall powered)?	No, the device is not electrical	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

K163529
Avery Dennison Corporation
Device Trade Name: Reliatect Post-op Dressing with CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm)
Contact Name: Lisa Bartakovics

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

DEFICIENCY LIST

(b)(4) Confidential and Proprietary Information - Deficiencies

[redacted]

(b)(4) Confidential and Proprietary Information - Deficiencies

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(b)(4) Confidential and Proprietary Information - Deficiencies

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

K163529
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Device Trade Name: Reliatect Post-op Dressing with CHG (8cm X 15cm), Reliatect Post-op Dressing With CHG (10cm X 25cm)
Contact Name: Lisa Bartakovics

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

DEFICIENCY LIST

(b)(4) Confidential and Proprietary Information - Deficiencies

[redacted]

(b)(4) Confidential and Proprietary Information - Deficiencies

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(b)(4) Confidential and Proprietary Information - Deficiencies

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
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.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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.

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
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

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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

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
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

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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,

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

MEMO TO THE RECORD
K163529/s01

DATE: March 13, 2017
FROM: Charles Durfor, Ph.D.
TO: The Record

OFFICE: ODE/CDRH
DIVISION: DSD/PRSB-2

COMPANY: Avery Dennison Corporation
DEVICE: Reliatect Post-op Dressing With CHG (8cm X 15cm) and (10cm X 25cm)

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

[redacted]

Charles N. Durfor -S
2017.03.13 13:49:48 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

From: Lisa Bartakovics
To: Bertram, James
Cc: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG
Date: (b) (4)
Attachments: image002.png

(b)(4) Confidential and Proprietary Information

Therefore, please find the following statement regarding (b) (4) :

(b)(4) Confidential and Proprietary Information

Please confirm this statement is sufficient to close out your request. Many thanks.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 28, 2017 at 9:09 AM, Bertram, James <James.Bertram@fda.hhs.gov> wrote:

> Dear Lisa,
>
> Thank you for your time. (b)(4) Confidential and Proprietary Information .
>
> Links to identify the NDA in CDER's public drug database is (b) (4) . This includes info about the NDA.
>
> For the orange book (where patent information is located), the link is (b) (4) (b)(4) Confidential and Proprietary Information .
>
> As noted, an email confirming our discussion would be needed for the administrative record. (b) (b) (4)

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Many thanks!

James

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 28, 2017 9:30 AM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

312 206 6159 please

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 28, 2017 at 8:21 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

If you will offer a phone number we will contact you.

Again thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Yes, please send me the call-in information.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



(b) (4) at 8:16 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Yes 9:30EST.

(b)(4) Confidential and Proprietary Information

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 28, 2017 9:11 AM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Mr. Durfor-

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Please advise if that is 9:30 AM EST ? Thank you.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 28, 2017 at 8:06 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics.

Many thanks again for your prompt responses to the issues associated with you 510(k) review.

(b) (4) [redacted]. Would you be available for a teleconference this morning from 9:30-10:00AM?

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Monday, March 27, 2017 3:49 PM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Dear Mr. Durfor-

I have incorporated your requested changes (b) (4)
Could you please confirm receipt of this e-mail. Much appreciated.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Mon, Mar 27, 2017 at 2:11 PM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

May I ask for a revised 510(k) Summary that includes (b) (4)

1) Please submit a revised document in which (b) (4)
(b)(4) Confidential and Proprietary Information .

2) Please submit a revised (b) (4) that states:

(b)(4) Confidential and Proprietary Information

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Dear Mr. Durfor-

I have attached a (b)(4) Confidential and Proprietary Information . Thank you and have a great day.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com

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On Mon, Mar 20, 2017 at 8:37 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Thank-you for your prompt response. I note (b) (4) made to (b) (4) (b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

In your response you state:

(b)(4) Confidential and Proprietary Information

Avery Dennison Response: Per the request of FDA, the (b) (4)
(b) (4)

(b)(4) Confidential and Proprietary Information

Many thanks!

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Good Afternoon Mr. Durfor-

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Please find the response to your comments in the attachment below. Would you be so kind as to confirm receipt of this e-mail? Thank you and have a great evening.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



(b) (4) at 9:50 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Yes, you may email the documents directly to me in pdf format. I will add them to the record.

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Dear Mr. Durfor-

Thank you for the rapid review. I have one question though, may I just e-mail the requested documents directly to you? Please advise. Have a great day.

Regards,

Lisa-

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



(b) (4) at 2:57 PM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Subsequent to a review of the information (b) (4), we have the following additional information requests. Based on the requirement to complete this review in 90 days, please submit your responses by Close of Business on (b) (4) If you have any questions or comments please feel free to contact me at (301) 796-6970 or charles.durfor@fda.hhs.gov .

1. Your response to (b) (4) included a (b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

2. Your response to deficiency #3 provided a (b) (4) (b) (4). "Section 7 of the *Performance Testing*" (b) (4)

(b)(4) Confidential and Proprietary Information

3. Your response to deficiency #4 provided a (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

This statement (b)(4) Confidential and Proprietary Information devices, i.e.,

- the instructions for use for SurgiClear (K121819), i.e.,

"SurgiClear provides an effective barrier against external contamination including fluids (waterproof), bacteria and yeast. The CHG and silver

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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incorporated within the silicone adhesive provides continuous antimicrobial activity over the recommended wear time against a variety of gram positive bacteria, gram negative bacteria and yeast including *S. aureus (MRSA), S. epidermidis, E. faecalis (VRE), K. pneumonia, P. aeruginosa, E. cloacae, C. albicans* and *C. tropicalis."*

(b)(4) Confidential and Proprietary Information

To be substantially equivalent to the cited predicate and reference devices, please submit a (b)(4) Confidential and Proprietary Information the following (b) (4) :

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

[redacted]

Charles Durfor
Chemist, Plastics and Reconstructive Surgery Devices Branch-2

Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)

Division of Surgical Devices

U.S. Food and Drug Administration
Tel: 301-796-6970
Charles.Durfor@fda.hhs.gov





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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

From: Bertram, James
To: lisa.bartakovics@averydennison.com
Cc: Durfor, Charles
Subject: RE: K163529 - Reliatect Post-op Dressing With CHG
Date: Tuesday, March 28, 2017 10:09:20 AM
Attachments: image002.png

Dear Lisa,
Thank you for your time. (b)(4) Confidential and Proprietary Information (b) (4) They new drug application (NDA) number is (b) (4)

Links to identify the NDA in CDER's public drug database is (b) (4). This includes info about the NDA.
For the orange book (where patent information is located), the link is (b) (4) (b) (4) bring up that NDA and its associated patents.

As noted, an email confirming our discussion would be needed for the administrative record. As (b) (4)

Many thanks!
James

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 28, 2017 9:30 AM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

312 206 6159 please

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 28, 2017 at 8:21 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:
If you will offer a phone number we will contact you.

Again thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 28, 2017 9:20 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Yes, please send me the call-in information.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 28, 2017 at 8:16 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Yes 9:30EST.

I do apologize.

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 28, 2017 9:11 AM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Mr. Durfor-

Please advise if that is 9:30 AM EST ? Thank you.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



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Dear Ms. Bartakovics.

Many thanks again for your prompt responses to the issues associated with you 510(k) review.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b) (4) . Would you be available for a teleconference this morning from 9:30-10:00AM?

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Monday, March 27, 2017 3:49 PM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Dear Mr. Durfor-

I have incorporated your requested changes into the attached (b) (4) . Could you please confirm receipt of this e-mail. Much appreciated.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com

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On Mon, Mar 27, 2017 at 2:11 PM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

May I ask for a revised 510(k) Summary that includes (b) (4)

1) Please submit a revised document in which the (b)(4) Confidential and Proprietary Information

2) Please submit a revised (b) (4) that states:

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

been performed.

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Dear Mr. Durfor-

I have attached a revised (b) (4) and (b) (4) that contain the (b) (4) (b) (4). Thank you and have a great day.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com

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(b) (4) at 8:37 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:

Dear Ms. Bartakovics

Thank-you for your prompt response. I note one change that must be made to (b) (4) (b) (4).

In your response you state:

Your response to deficiency #3 provided a (b) (4) *document* (b) (4) *" states:*

(b)(4) Confidential and Proprietary Information

Avery Dennison Response: Per the request of FDA, (b) (4) have been modified to state the following:

(b)(4) Confidential and Proprietary Information

(b) (4) .. Please submit a revised (b) (4) that is consistent (b) (4)

(b)(4) Confidential and Proprietary Information

Many thanks!

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: (b) (4)
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

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Please find the response to your comments in the attachment below. Would you be so kind as to confirm receipt of this e-mail? Thank you and have a great evening.

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



On Tue, Mar 14, 2017 at 9:50 AM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:
Dear Ms. Bartakovics

Yes, you may email the documents directly to me in pdf format. I will add them to the record.

Many thanks!

C. Durfor

From: Lisa Bartakovics [mailto:lisa.bartakovics@averydennison.com]
Sent: Tuesday, March 14, 2017 10:49 AM
To: Durfor, Charles
Subject: Re: K163529 - Reliatect Post-op Dressing With CHG

Dear Mr. Durfor-

Thank you for the rapid review. I have one question though, may I just e-mail the requested documents directly to you? Please advise. Have a great day.

Regards,
Lisa-

Regards,

Lisa Bartakovics | Senior Director of Global Regulatory Affairs | Vancive Medical Technologies| an Avery Dennison business | 20 North Wacker Drive, Suite 2240, Chicago, Illinois 60606| 312-629-4608 | Cell 312-206-6159| lisa.bartakovics@averydennison.com



(b) (4) at 2:57 PM, Durfor, Charles <Charles.Durfor@fda.hhs.gov> wrote:
Dear Ms. Bartakovics

Subsequent to a review of the information provided in supplement 1, we have the following additional information requests. Based on the requirement to complete this review in 90 days, please submit your responses by Close of Business on (b) (4). If you have any questions or comments please feel free to contact me at (301) 796-6970 or charles.durfor@fda.hhs.gov .

1. Your response to deficiency #6 included (b)(4) Confidential and Proprietary Information

2. Your response to deficiency #3 provided a (b)(4) Confidential and Proprietary Information "Section 7 of the *Performance Testing" states:*

(b)(4) Confidential and Proprietary Information

3. Your response to deficiency #4 (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

- the instructions for use for SurgiClear (K121819), i.e.,

  "SurgiClear provides an effective barrier against external contamination including fluids (waterproof), bacteria and yeast. The CHG and silver incorporated within the silicone adhesive provides continuous antimicrobial activity over the recommended wear time against a variety of gram positive bacteria, gram negative bacteria and yeast including *S. aureus (MRSA), S. epidermidis, E. faecalis (VRE), K. pneumonia, P. aeruginosa, E. cloacae, C. albicans* and *C. tropicalis."*

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

[redacted]

Charles Durfor
Chemist, Plastics and Reconstructive Surgery Devices Branch-2

Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Surgical Devices
U.S. Food and Drug Administration
Tel: 301-796-6970
Charles.Durfor@fda.hhs.gov





Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.

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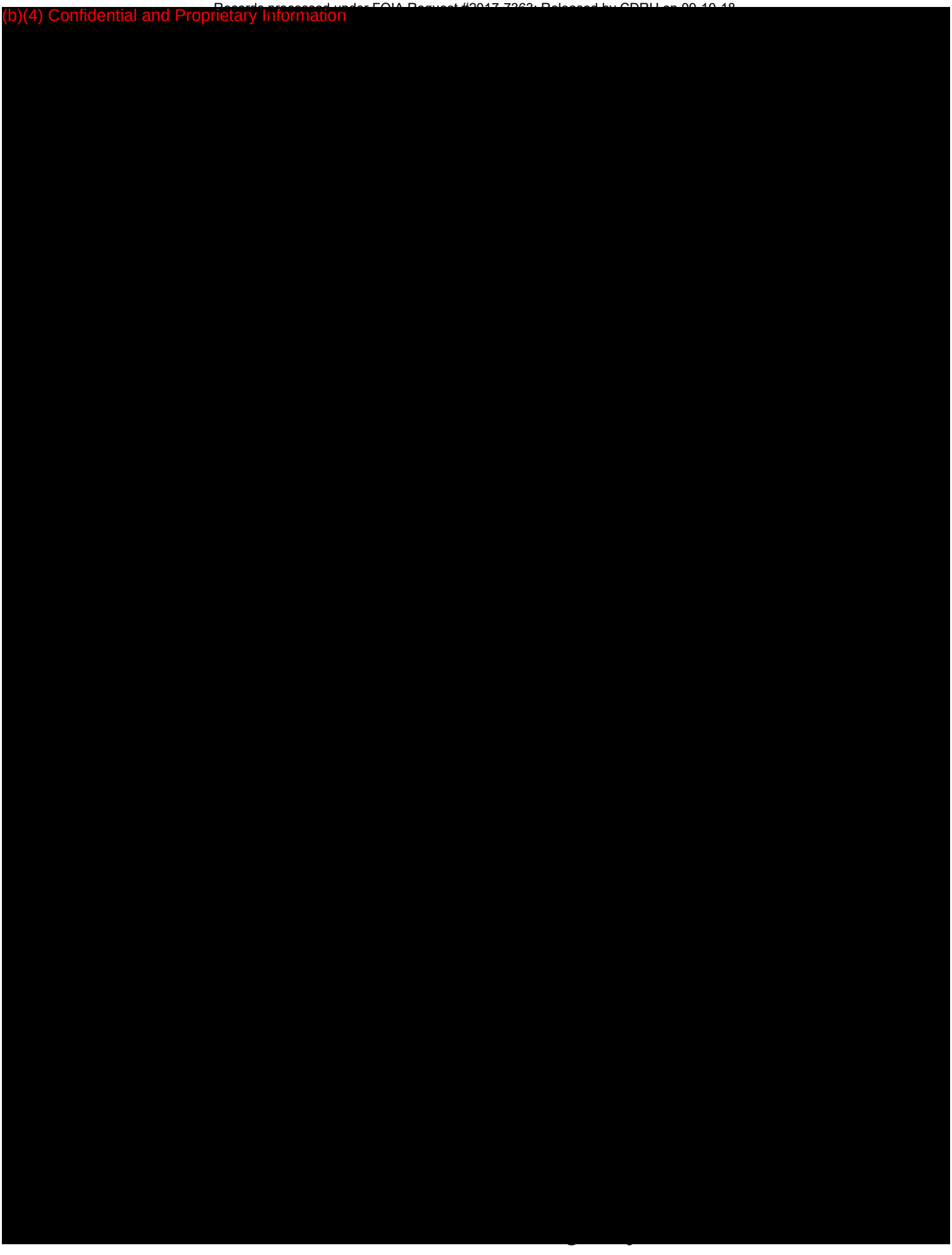
Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-19-18

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

[redacted]

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Surgical Devices
U.S. Food and Drug Administration
Tel: 301-796-6970
Charles.Durfor@fda.hhs.gov





Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

AVERY DENNISON

7100 Lindsay Drive
Mentor, Ohio 44060
Phone: (440) 358-2600
Fax: (440) 358-2895

(b)(4) Confidential and Proprietary Information

Mr. Charles Durfor
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Avery Dennison 510(k) Application K163529
Device: ReliaTect Post-Op Dressing with CHG

Dear Mr. Durfor,

We have reviewed your request for additional information regarding the Traditional 510(k) submission for the ReliaTect Post-Op Dressing with CHG (reference K163529) and have provided detailed responses to each of your points below. Based upon your requests, we are enclosing the required documents to complete review of our submission. If you need any further information, please direct such correspondence to me at the e-mail address or telephone number provided below. Thank you.

Best Regards,

Lisa Bartakovics
Director of Global Regulatory Affairs
Avery Dennison Corporation
T: 312-206-6159 e-mail: Lisa.Bartakovics@averydennison.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Please Note: (b)(4) Confidential and Proprietary Information are provided below in bold, italic, type (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Please find the requested (b)(4) Confidential and Proprietary attached for your review.

2. ***Your response to deficiency #3 provided*** (b)(4) Confidential and Proprietary Information ***document "Section 7 of the Performance Testing" states:***

(b)(4) Confidential and Proprietary Information

Please find a revised (b)(4) Confidential and Proprietary Information attached for your review.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

[redacted]

- *the instructions for use for SurgiClear (K121819), i.e.,*

  "SurgiClear provides an effective barrier against external contamination including fluids (waterproof), bacteria and yeast. The CHG and silver incorporated within the silicone adhesive provides continuous antimicrobial activity over the recommended wear time against a variety of gram positive bacteria, gram negative bacteria and yeast including S. aureus (MRSA), S. epidermidis, E. faecalis (VRE), K. pneumonia, P. aeruginosa, E. cloacae, C. albicans and C. tropicalis."

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information

Avery Dennison Response: Please find a revised (b)(4) Confidential and Proprietary Information that

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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 including: Staphylococcus aureus, Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Enterococcus faecalis (VRE), Escherichia coli, Pseudomonas aeruginosa, Enterobacter aerogenes, Klebsiella

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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 was performed and the presence of CHG within the dressing inhibits microbial growth.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

FDA/CDRH/DCC
DEC 16 2016
RECEIVED

K163529

Avery Dennison Corporation
7100 Lindsay Drive
Building 14
Mentor, OH 44060
Tel: +1 (440) 534-6000

Traditional 510(k) Notification

December 15, 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Document Mail Center WO66-G609
Silver Spring, MD 20993-0002

Subject: 510(k) Notification for the ReliaTect™ Post-Op Dressing with CHG

Dear Madam or Sir:

Pursuant to 21 CFR Part 807, Avery Dennison is submitting two copies of this Traditional 510(k) for your review. An electronic copy of the submission is provided to facilitate the review. The eCopy is an exact duplicate of the paper copy. Please find the paper and electronic copy enclosed. Thank you.

Regards,

(b) (6)

Lisa Bartakovics
Director of Global Regulatory Affairs
Avery Dennison
Phone: +1 (312) 206-6159
E-mail: Lisa.Bartakovics@averydennsion.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2019. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

AVERY DENNISON
20 N. Wacker
Suite 2240
Chicago
IL 60606
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****2269

2. CONTACT NAME
Lisa Bartakovics
2.1 E-MAIL ADDRESS
Lisa.Bartakovics@averydennison.com
2.2 TELEPHONE NUMBER (include Area code)
(b) (6)
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

09-Nov-2016

Form FDA 3601 (08/16)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
December 15, 2016	MD6091719	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Avery Dennison Corporation	3003764829		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	440-534-6000		
Street Address	**FAX Number *(including area code)***		
7100 Lindsay Drive Bldg 14	312-629-4601		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Mentor	OH	44060	USA
Contact Name			
Lisa Bartakovics			
Contact Title	**Contact E-mail Address**		
Director of Global Regulatory Affairs	lisa.bartakovics@averydennison.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118
FDA Publishing Services (301) 443-6740 EF

Records processed under FOIA Request #2017-7368, Released by CDRH on 09-10-18.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7365, Released by CDRH on 09-10-18.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K121819	1	SurgiClear™Antimicrobial Clear Silicone Adhesive Dressing withChlorhexidine and Silver	1	Covalon Technologies Incorporated
2	K113836 (Reference Device)	2	Benehold CHG Transparent Film Dressing	2	Avery Dennison Belgie BVBA
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Dressing, Wound

	Trade or Proprietary or Model Name for This Device		Model Number
1	ReliaTect™ Post-Op Dressing with CHG (8cm x 15cm)	1	MED 9903S
2	ReliaTect™ Post-Op Dressing with CHG (10cm x 25cm)	2	MED 9904S
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FRO

C.F.R. Section *(if applicable)*:

Classification Panel: General and Plastic Surgery

Device Class

☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Indications *(from labeling)*

ReliaTect™ Post-Op Dressing with CHG (Chlorhexidine Gluconate) is intended to cover and protect, against external contamination, post-operative, debrided or partial thickness wounds with light to moderate exudate, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns. ReliaTect™ Post-Op Dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days. ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Note: Submission of the information requested in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3003764829	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Avery Dennison Corporation		Establishment Registration Number: 3003764829
Division Name *(if applicable)*		Phone Number *(including area code)*: (b) (4)
Street Address: 7100 Lindsay Drive, Bldg 14		FAX Number *(including area code)*: (b) (4)
City: Mentor	State / Province: OH	ZIP Code: 44060 Country: USA
Contact Name: Lisa Bartakovics	Contact Title: Director of Global Regulatory Affairs	Contact E-mail Address: lisa.bartakovics@averydennison.com

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4) Confidential and Proprietary Information

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7368, Released by CDRH on 09-10-18.

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

(b)(4) Confidential and Proprietary Information

[redacted]

Please include any additional standards to be cited on a separate page.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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SECTION I UTILIZATION OF STANDARDS

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(b)(4) Confidential and Proprietary Information

2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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(b)(4) Confidential and Proprietary Information

Page 6

Questions? Contact FDA/CDRH/OCE/DID at C call 301-796-8118.

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Avery Dennison Corporation
7100 Lindsay Drive
Building 14
Mentor, OH 44060
Tel: +1 (440) 534-6000

Traditional 510(k) Notification

December 15, 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Document Mail Center WO66-G609
Silver Spring, MD 20993-0002

Subject: 510(k) Notification for the ReliaTect™ Post-Op Dressing with CHG

Dear Madam or Sir:

Pursuant to 21 CFR Part 807, Avery Dennison is submitting two copies of this Traditional 510(k) for your review. An electronic copy of the submission is provided to facilitate the review. The eCopy is an exact duplicate of the paper copy. Please find the paper and electronic copy enclosed. Thank you.

Regards,

(b) (6)

Lisa Bartakovics
Director of Global Regulatory Affairs
Avery Dennison
Phone: +1 (312) 206-6159
E-mail: Lisa.Bartakovics@averydennsion.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

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, which serves as a preservative within the device.

5. Indications for Use

The ReliaTect™ Post-Op Dressing with CHG is intended to cover and protect, against external contamination, post-operative, debrided, or partial thickness

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

wounds with light to moderate exudates, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

ReliaTect™ Post-Op dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips) orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days.

ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

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 as is the fundamental scientific technology that the CHG acts as a preservative within the 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 was performed and supports *in vitro* antimicrobial performance of the ReliaTect™ Post-Op Dressing with CHG. Results indicate that the dressing is effective against the required organisms required within USP<51>. Both the ReliaTect™ Post-Op Dressing with CHG and Covalon SurgiClear™ dressings meet the requirements for preservative effectiveness against the organisms listed within USP <51>.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Global Regulatory Affairs of Avery Dennison Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6) [redacted]

Lisa Bartakovics

December 15, 2016

K_____

Questions? Contact FDA/CDRH/OCE/DIP at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Section 7- Class III Summary and Certifications

This section is not applicable, since the ReliaTect™ Post-Op Dressing with CHG is an unclassified device, Product Code FRO.

Questions? Contact FDA/CDRH at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Section 8- Financial Certification or Disclosure Statement

This section is not applicable, as no clinical studies were performed for the ReliaTect™ Post-Op Dressing with CHG.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4) Confidential and Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	(b) (4)	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	(b) (4)	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1: Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

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JUSTIFICATION

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4) Confidential and Proprietary Information

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] (b) (4)		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

JUSTIFICATION

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JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4) Confidential and Proprietary Information

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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FDA Recognition number [3] (b) (4)		
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

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JUSTIFICATION

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JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

(b)(4) Confidential and Proprietary Information

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FDA Recognition number [3] (b) (4)		
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

[redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) Confidential and Proprietary Information

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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

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Section 10 – Executive Summary

Avery Dennison received clearance for its Benehold™ IV dressing containing CHG in 2012 (K113836). Avery successfully developed a manufacturing method (b) (4)

(b)(4) Confidential and Proprietary Information

The device technology, formulation and manufacturing methods for the ReliaTect™ Post-Op dressing are the same as the IV dressing as cleared in submission K113836. Therefore, the Benehold™ IV dressing containing CHG may be considered the reference device for the ReliaTect™ Post-Op Dressing with CHG.

(b)(4) Confidential and Proprietary Information

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the commercially available Covalon SurgiClear™ device (K121819). Bench testing studies, including (b) (4) the two devices have comparable performance. The Intended Use of the ReliaTect™ is equivalent to the SurgiClear™ device as is the fundamental scientific technology (b) (4)

(b)(4) Confidential and Proprietary Information

ReliaTect™ Post-Op Dressing with CHG (Chlorhexidine Gluconate) is intended to cover and protect, against external contamination, post-operative, debrided or partial thickness wounds with light to moderate exudate, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

ReliaTect™ Post-Op Dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days.

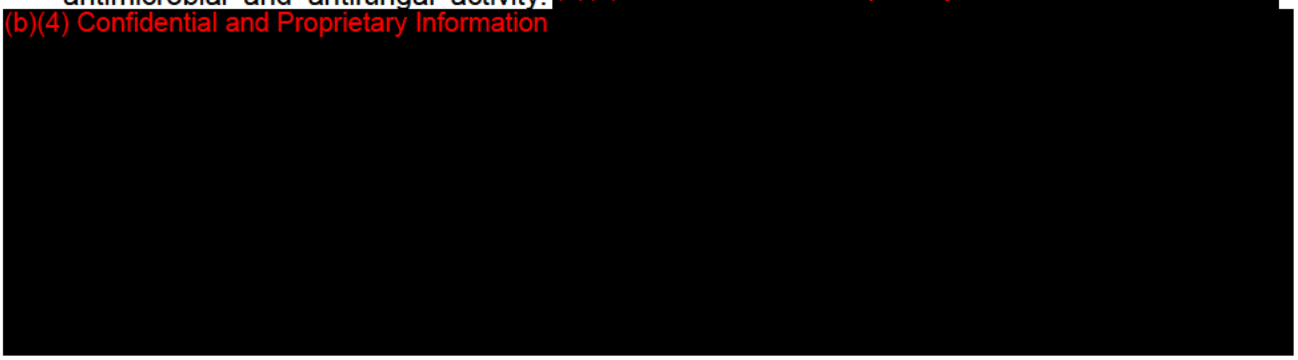
ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

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The dressing consists of a transparent film with an acrylic adhesive which contains Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



Indications for Use:

ReliaTect™ Post-Op Dressing with CHG (Chlorhexidine Gluconate) is intended to cover and protect, against external contamination, post-operative, debrided or partial thickness wounds with light to moderate exudate, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

ReliaTect™ Post-Op Dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days.

ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

A comparison of the ReliaTect™ Post-Op Dressing with CHG and the predicate Covalon SurgiClear™ device may be found in Table 10.1. The comparison shows that the ReliaTect™ Post-Op Dressing with CHG and the Covalon SurgiClear™ device are substantially equivalent. The detailed comparison of the components of each device is described in Table 10.2.

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Table 10.1: Comparison of Proposed and Predicate Device			
Characteristic	Proposed ReliaTect™ Post-Op Dressing with CHG	Predicate Covalon SurgiClear™ device	Conclusion
Intended Use	(b)(4) Confidential and Proprietary Information	SurgiClear™ is intended to cover and protect wound sites, against external contamination, including post-operative, debrided or partial thickness wounds such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns. SurgiClear™ can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. SurgiClear™ may also be used to cover and secure primary dressings. SurgiClear™ inhibits microbial colonization and suppresses microbial regrowth under the dressing.***	Equivalent
(b)(4) Confidential and Proprietary Information		Dressing sizes: 4 cm x 4 cm 4 cm x 7 cm 4 cm x 13 cm 10 cm x 12 cm 6 cm x 20 cm 6 cm x 25 cm 6 cm x 30 cm	Equivalent

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Table 10.1: Comparison of Proposed and Predicate Device			
Characteristic	Proposed ReliaTect™ Post-Op Dressing with CHG	Predicate Covalon SurgiClear™ device	Conclusion
(b)(4) Confidential and Proprietary Information			
(b)(4) Confidential and Proprietary Information		Sterilized by Ethylene Oxide	Equivalent, both products are sterile
(b)(4) Confidential and Proprietary Information			

****Note: The Indications for Use within the current SurgiClear device differ slightly from the 510(k) summary.*

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Table 10.2: (b) (4)	of Proposed and Predicate Devices	
(b)(4) Confidential and Proprietary Information	ReliaTect™ Post-Op Dressing with CHG	Covalon SurgiClear™ device
	(b)(4) Confidential and Proprietary Information	

The technological characteristics of the ReliaTect™ Post-Op Dressing with CHG and the predicate Covalon SurgiClear™ device are equivalent in that they are dressings used to cover and protect catheter sites and secure devices to the skin (b) (4)
(b)(4) Confidential and Proprietary Information

Biocompatibility testing was performed according to ISO 10993 (b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information

Performance testing was completed on various characteristics to ensure product requirements were met as well as for comparison against similar characteristics on the predicate product. Acceptance criteria were met for all characteristics and comparison against the predicate showed 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

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information - Protocol Study

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Section 11 – Device Description

Device Description

The ReliaTect™ Post-Op Dressing with CHG is intended to cover and protect, against external contamination, post-operative, debrided, or partial thickness wounds with light to moderate exudates, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

ReliaTect™ Post-Op dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips) orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days.

ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

The dressing consists of a transparent film with an acrylic adhesive which contains Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Device Market Presentation

The ReliaTect™ Post-Op Dressing with CHG will be offered in (b) (4) as described in Table 11.1. The difference between each model is the size of the dressing. The thickness of the dressing is the same in all models. There are no accessories associated with this device.

Table 11.1
ReliaTect™ Post-Op Dressing with CHG Model Information

(b)(4) Confidential and Proprietary Information

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Device Components and Patient Contacting Materials

(b)(4) Confidential and Proprietary Information

[redacted]

Table 11.2
ReliaTect™ Post-Op Dressing with CHG Components

Component	Patient Contacting?	Material

(b)(4) Confidential and Proprietary Information

[redacted]

A diagram of the device along with identification of components is presented in Figure 11.1.

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Figure 11.1 (a)
ReliaTect™ Post-Op Dressing with CHG

(b)(4) Confidential and Proprietary Information

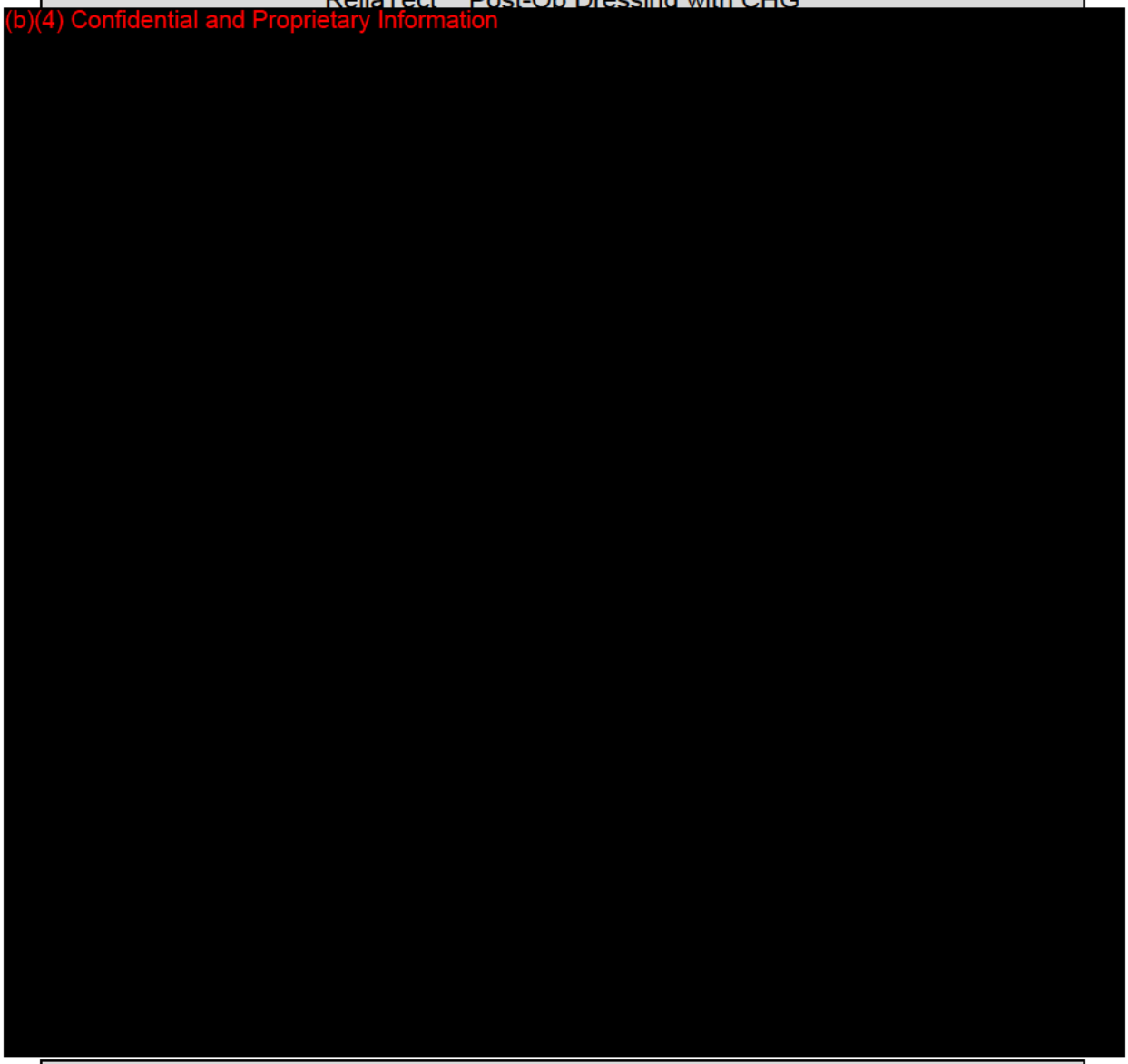
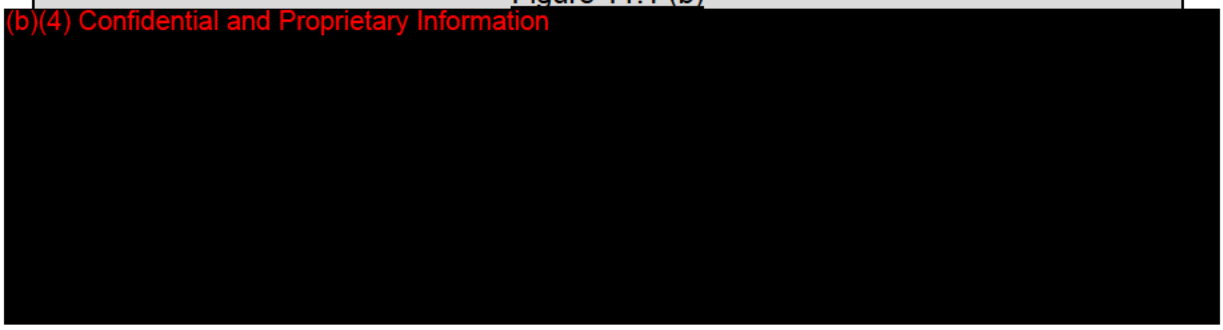


Figure 11.1 (b)

(b)(4) Confidential and Proprietary Information



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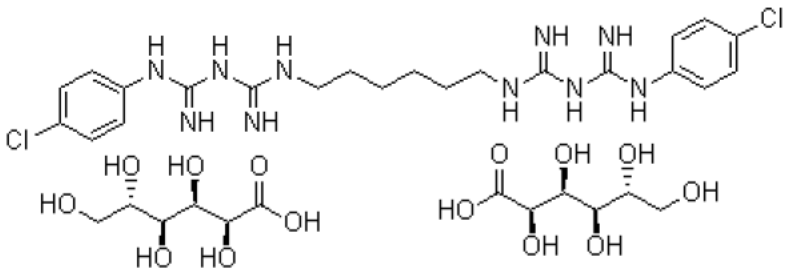
(b)(4) Confidential and Proprietary Information

The antimicrobial agent found in the ReliaTect™ Post-Op Dressing with CHG is Chlorhexidine Gluconate or Chlorhexidine di-gluconate (CHG). (b) (4)

(b)(4) Confidential and Proprietary Information

Figure 11.3

Molecular Structure and Chemical Formula of Chlorhexidine Gluconate



$C_{22}H_{30}Cl_2N_{10}\cdot 2C_6H_{12}O_7$

(b)(4) Confidential and Proprietary Information

CHG is an antiseptic that has been used in a wide range of products for its ability to provide antimicrobial protection.

The mechanism of action is well-known (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

Cases of microbial resistance to Chlorhexidine Gluconate (CHG) are known to occur

(b)(4) Confidential and Proprietary Information

(b) (4) Because of CHG's potency and ability to affect a broad range of organisms, it was selected as the antimicrobial for incorporation into the ReliaTect™ Post-Op Dressing with CHG.

(b) (4) Antimicrobial Agent (b) (4)

Chlorhexidine gluconate (CHG) is widely used biocide, substantively for its broad-spectrum efficacy, substantivity for the skin and for its low irritation. At a low concentration, CHG is bacteriostatic, or inhibits the reproduction of bacteria. At high concentration, CHG is bactericidal, or kills bacteria. (b) (4)

(b)(4) Confidential and Proprietary Information

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Table 11.3

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

The ReliaTect™ Post-Op Dressing with CHG adhesive has been formulated to contain (b)(4) Confidential and Proprietary Information

Table 11.4

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section 12 – Substantial Equivalence Discussion

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the commercially available Covalon SurgiClear™ device (K121819). Animal Studies, Bench testing and antimicrobial efficacy testing demonstrate the two devices have comparable performance. The Intended Use of the ReliaTect™ is equivalent to the SurgiClear™ device as is the fundamental scientific technology that the (b)(4) (b)(4) Confidential and Proprietary Information

The ReliaTect™ Post-Op Dressing with CHG is intended to cover and protect, against external contamination, post-operative, debrided, or partial thickness wounds with light to moderate exudates, such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

ReliaTect™ Post-Op dressing can be used to cover and protect wound closure devices (i.e. sutures, staples, clips) orthopedic pins, fixtures and wires as well as drains. ReliaTect™ Post-Op Dressing may also be used to cover and secure primary dressings. The dressing can be worn for up to 7 days.

ReliaTect™ Post-Op Dressing inhibits microbial colonization and suppresses microbial re-growth under the dressing.

The dressing consists of a transparent film with an acrylic adhesive which contains Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the Covalon SurgiClear™ device in function, performance and Intended Use. The predicate device is listed in Table 12.1.

Table 12.1
Covalon SurgiClear™ device

Common Name	Wound Dressing, Antimicrobial
Trade Name	SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver
510(k) Submitted/Holder	Covalon Technologies Inc.
Device Classification	Antimicrobial Dressing, Unclassified
510(k) Number	K121819

A detailed comparison of the proposed ReliaTect™ Post-Op Dressing with CHG and the predicate Covalon SurgiClear™ dressing is provided in Table 12.2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PDSTATUS@fda.hhs.gov or call 301-796-8118.

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Table 12.2
Comparison of Proposed and Predicate Device

Device	Proposed ReliaTect™ Post-Op Dressing with CHG	Predicate Covalon SurgiClear™ device	Conclusion
Intended Use	(b)(4) Confidential and Proprietary Information	SurgiClear™ is intended to cover and protect wound sites, against external contamination, including post-operative, debrided or partial thickness wounds such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns. SurgiClear™ can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. SurgiClear™ may also be used to cover and secure primary dressings. SurgiClear™ inhibits microbial colonization and suppresses microbial regrowth under the dressing.	Equivalent
(b)(4) Confidential and Proprietary Information		Dressing sizes: 4 cm x 4 cm 4 cm x 7 cm 4 cm x 13 cm 10 cm x 12 cm 6 cm x 20 cm 6 cm x 25 cm 6 cm x 30 cm	Equivalent
		(b)(4) Confidential and Proprietary Information	

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Table 12.2
Comparison of Proposed and Predicate Device

Device	Proposed ReliaTect™ Post-Op Dressing with CHG	Predicate Covalon SurgiClear™ device	Conclusion
(b)(4) Confidential and Proprietary Information			
(b)(4) Confidential and Proprietary Information		Sterilized by Ethylene Oxide gas	Equivalent, both dressings are sterile and achieve a SAL of 10^{-6}
(b)(4) Confidential and Proprietary Information			

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 12.2
Comparison of Proposed and Predicate Device

Device	Proposed ReliaTect™ Post-Op Dressing with CHG	Predicate Covalon SurgiClear™ device	Conclusion
Operational Technology	(b)(4) Confidential and Proprietary Information	Adhesive dressing used to cover and protect wound sites, against external contamination, including post-operative, debrided or partial thickness wounds such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.	Equivalent
(b)(4) Confidential and Proprietary Information		(b)(4) Confidential and Proprietary Information	
(b)(4) Confidential and Proprietary Information			

Questions? Contact FDA/CDRH/OCE/DID at CDRHPOSTATUS@fda.hhs.gov or call 301-796-8118.

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Performance Discussion

The ReliaTect™ Post-Op Dressing with CHG and the Covalon SurgiClear™ device have substantially equivalent performance. (b)(4) Confidential and Proprietary Information [redacted] Testing of the devices resulted in comparable or equivalent results.

(b)(4) Confidential and Proprietary Information [redacted] further supporting the point that the ReliaTect™ and SurgiClear™ devices are substantially equivalent.

(b)(4) Confidential and Proprietary Information [redacted] indicate superior performance therefore both devices may be considered equivalent.

Substantial Equivalence Comparison Summary

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the commercially available Covalon SurgiClear™ device. Animal Studies, Bench testing and antimicrobial efficacy testing demonstrate the two devices have comparable performance. The Intended Use of the ReliaTect™ is equivalent to the SurgiClear™ device as is the fundamental scientific technology. (b) (4) [redacted] safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PDSTATUS@fda.hhs.gov or call 301-796-8118.

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Section 13 - Proposed Labeling

The ReliaTect™ Post-Op Dressing with CHG is substantially equivalent to the commercially available Covalon SurgiClear™ device (K121819). (b) (4) (b)(4) Confidential and Proprietary Information (b) (4) The Intended Use of the ReliaTect is equivalent to the SurgiClear™ device (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information

The labeling, (b)(4) Confidential and Proprietary Information (b) (4) are equivalent (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information In the case of the ReliaTect™ device, (b)(4) Confidential and Proprietary Information (b) (4)

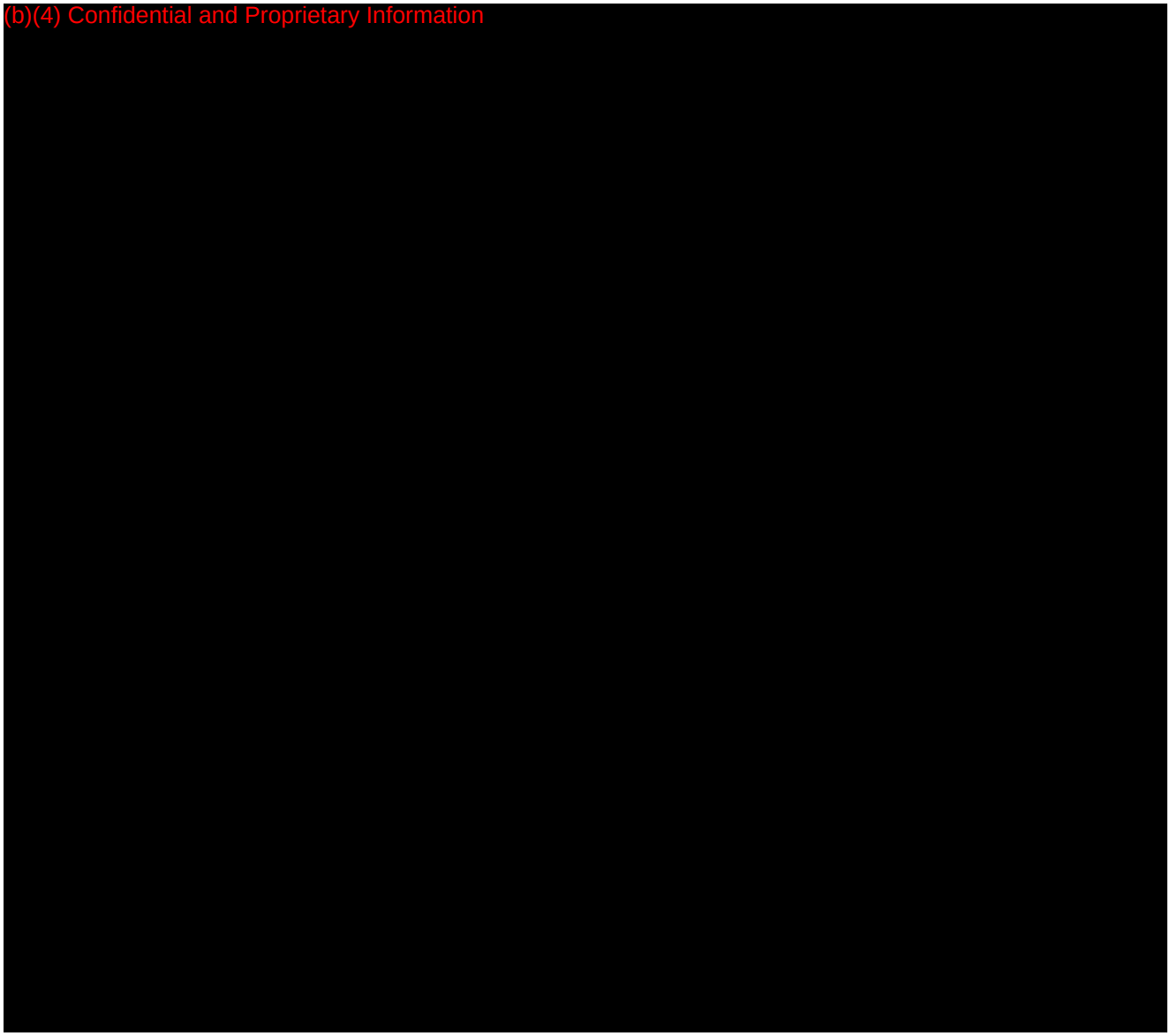
Table 13.1
Proposed and Predicate Labeling

Device	Label	Reference
Proposed: ReliaTect™ Post Op Dressing with CHG (b) (4)	Pouch	(b)(4) Confidential and Proprietary Information
	Primary Carton	
Proposed: ReliaTect™ Post Op Dressing with CHG (b) (4)	Pouch	
	Primary Carton	
Proposed: ReliaTect™ Post Op Dressing with CHG (b) (4)	Instructions for Use	
Predicate: SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver	Pouch	
	Primary Carton	
	Instructions for Use	
Predicate: SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver	Marketing Material	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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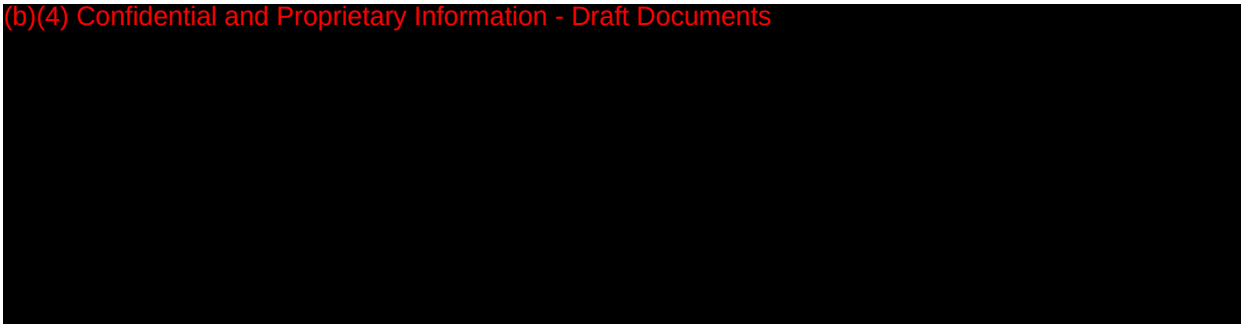
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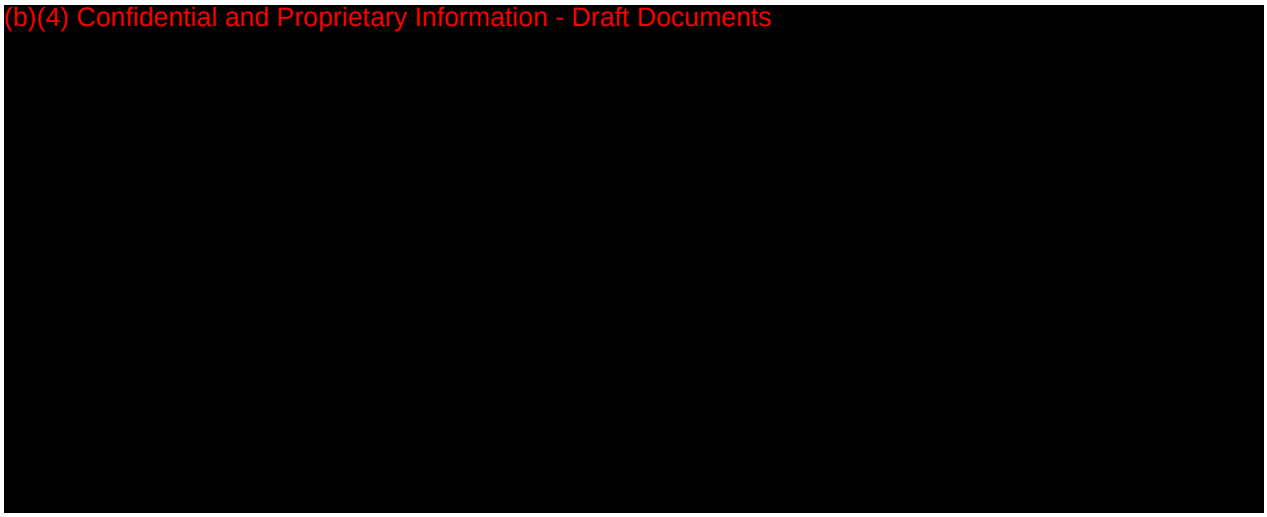
Records processed under FOIA Request #2017-7363; Released by CDRH on 09-19-18

(b)(4) Confidential and Proprietary Information - Draft Documents

[redacted]

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information - Draft Documents



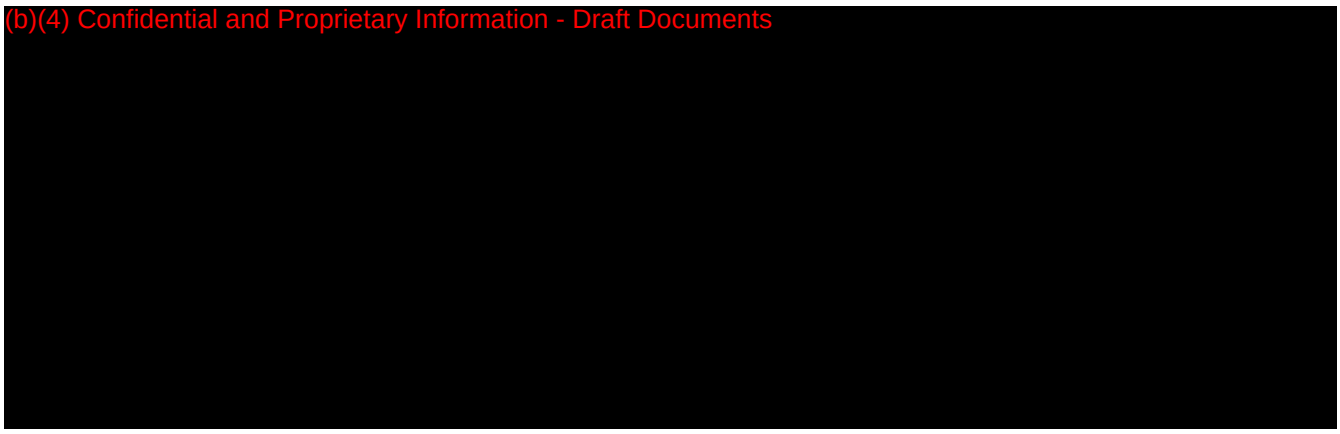
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

[redacted]

(b)(4) Confidential and Proprietary Information - Draft Documents

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information - Draft Documents



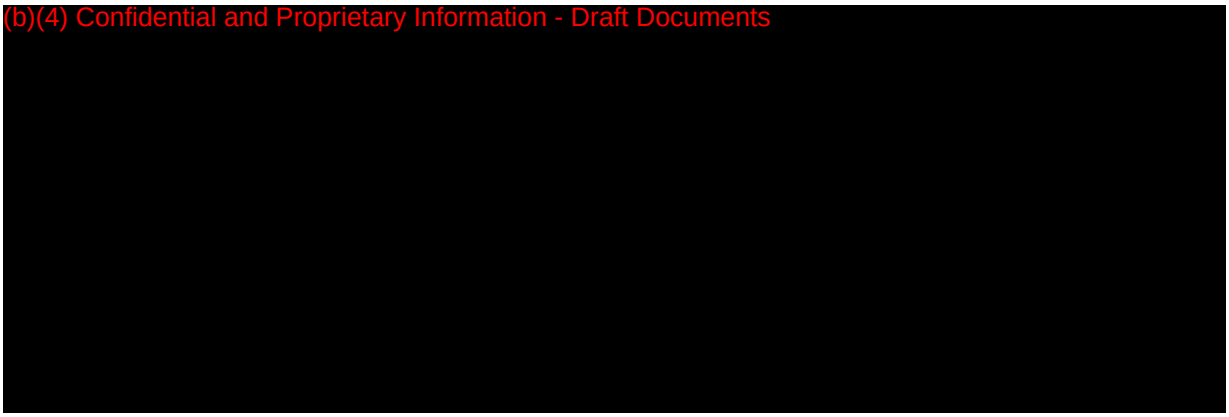
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Draft Documents

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

(b)(4) Confidential and Proprietary Information - Draft Documents

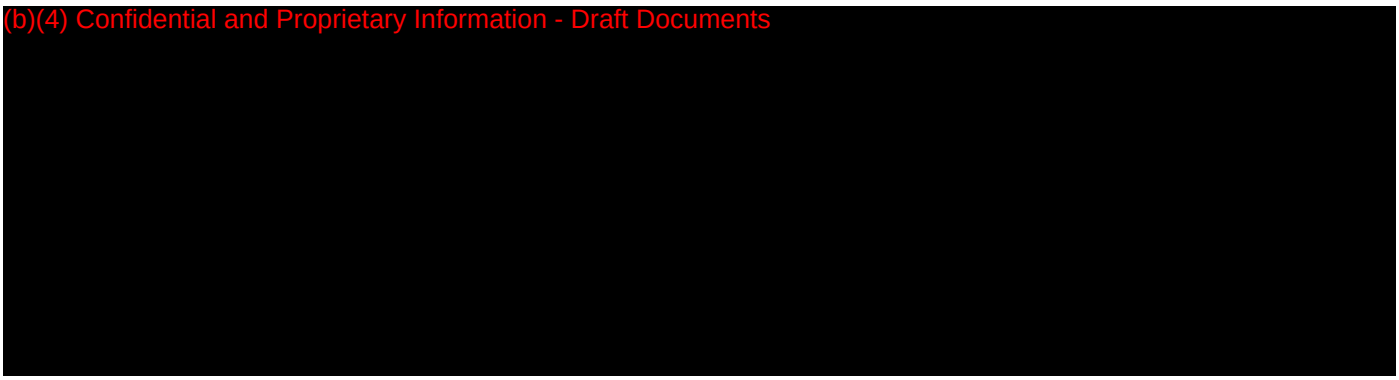


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Draft Documents

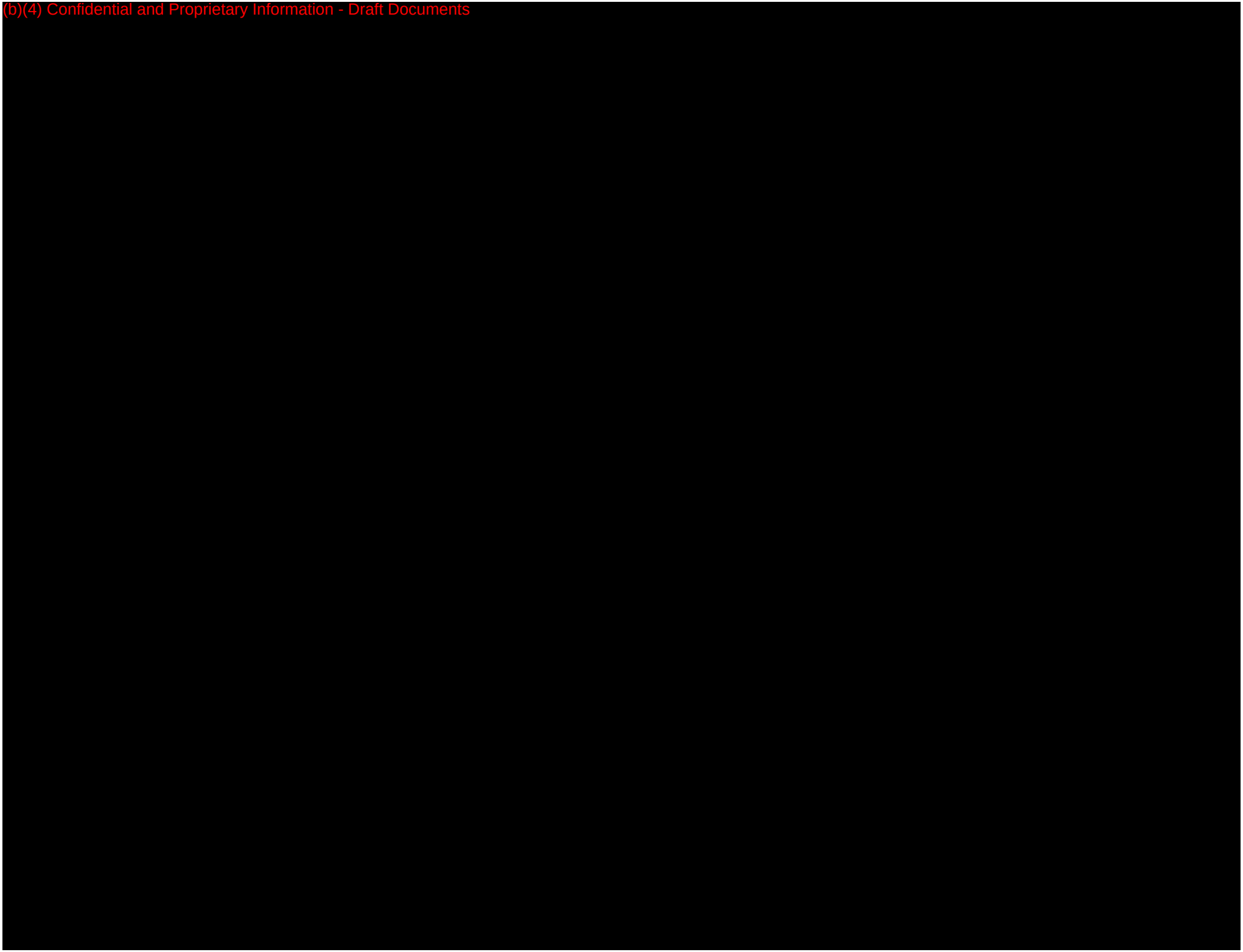
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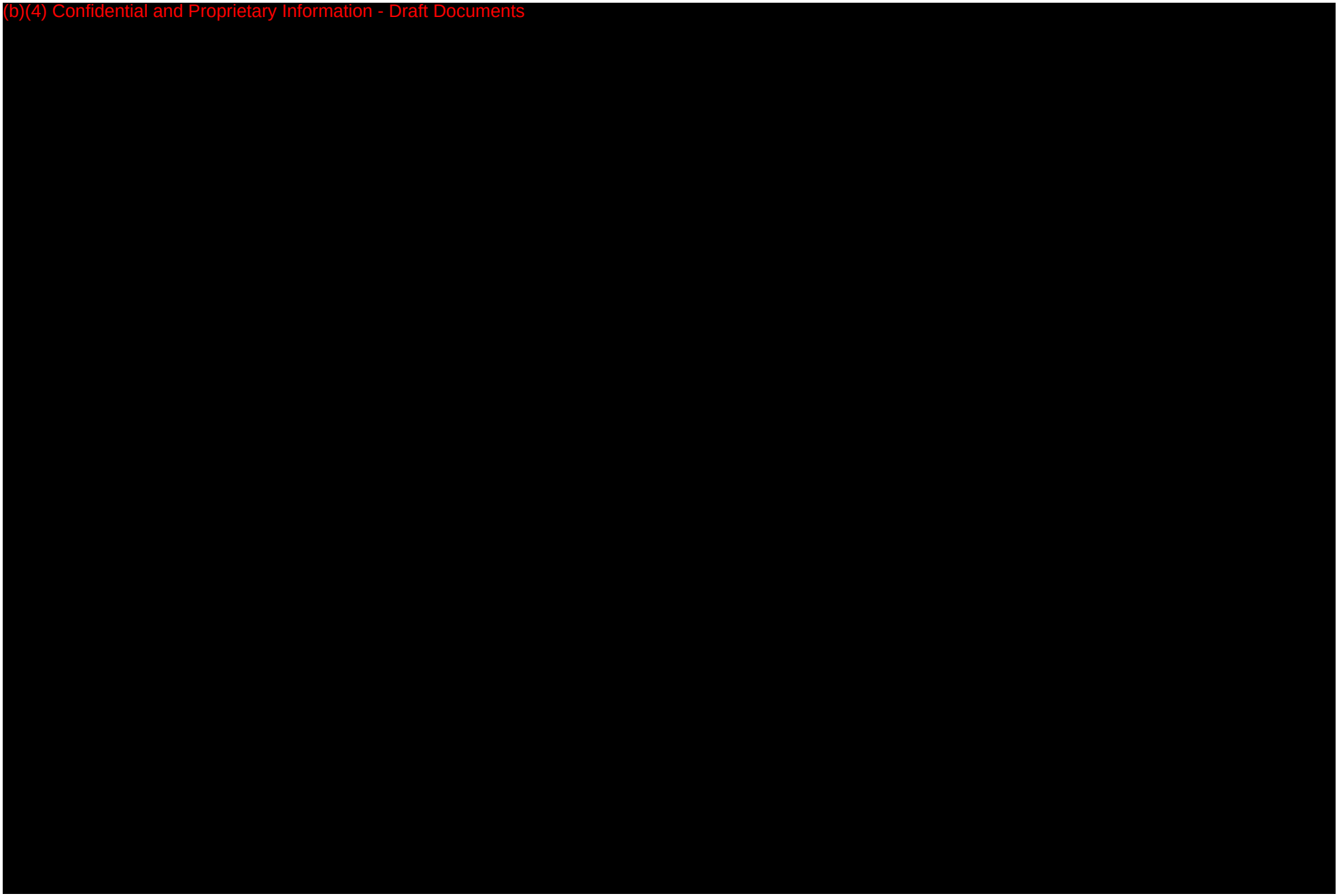


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Draft Documents



(b)(4) Confidential and Proprietary Information - Draft Documents



Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Attachment 13.6
Predicate, SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver- Pouch

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

covalon

SurgiClear™

2½ in x 12in 6cm x 30cm

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

Pansement Adhésif Antimicrobien en Silicone Transparent à la Chlorhexidine et à L'argent

Apósito Antimicrobiano Transparente Adhesivo de Silicona con Clorhexidina y Plata

LOT# PS16590 EXP: SEP 2018

Rx Only

#TWBD1025

STERILE EO

8 25439 01044 0

Manufactured in the USA for/Fabriqué aux États-Unis pour/Fabricado en USA para: Covalon Technologies Inc. Mississauga (Ontario) L4Z 3E6 Canada www.covalon.com
SurgiClear™ is a trademark of Covalon Technologies.

LS-105-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Attachment 13.7
Predicate, SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver- Primary Carton

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

covalon

covalon

SurgiClear™

SurgiClear ™

2½ in x 12in **6cm x 30cm**

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

Pansement Adhésif Antimicrobien en Silicone Transparent à la Chlorhexidine et à L'argent

Apósito Antimicrobiano Transparente Adhesivo de Silicona con Clorhexidina y Plata

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

LS108-0

8 25439 01041 9

Manufactured in the USA for/Fabriqué aux États-Unis pour/Fabricado en USA para:
Covalon Technologies Inc.
Mississauga (Ontario)
L4Z 3E6 Canada
www.covalon.com
SurgiClear™ is a trademark of Covalon Technologies.

covalon

SurgiClear™

SurgiClear™

2½ in x 12in 6cm x 30cm

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

Pansement Adhésif Antimicrobien en Silicone Transparent à la Chlorhexidine et à L'argent

Apósito Antimicrobiano Transparente Adhesivo de Silicona con Clorhexidina y Plata

Rx Only

#TWBD1025

STERILE EO

25 Pcs

LOT# PS16590-R
EXP SEP 2018

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Attachment 13.8
Predicate, SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver- Instructions for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

covalon

SurgiClear™

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

INSTRUCTIONS FOR USE

Description

SurgiClear™ is an Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver used to cover and protect wound sites and wound closure devices. SurgiClear™ also secures primary dressings to skin. The dressing consists of a clear polyurethane film coated with an antimicrobial silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts. SurgiClear's antimicrobial silicone adhesive reduces incidence of epidermal stripping and is up to ten times less painful upon removal compared to dressings containing acrylic adhesives.

SurgiClear™ provides an effective barrier against external contamination including fluids (waterproof), bacteria, and yeast. The chlorhexidine and silver incorporated within the silicone adhesive provides continuous antimicrobial activity over the recommended wear time against a variety of gram positive bacteria, gram negative bacteria and yeast, including *Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Enterococcus faecalis (VRE), Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter cloacae, Candida albicans,* and *Candida tropicalis*.

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.

Indications for Use

SurgiClear™ is intended to cover and protect wound sites, against external contamination, including post-operative, debrided or partial thickness wounds such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

SurgiClear™ can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. SurgiClear™ may also be used to cover and secure primary dressings.

SurgiClear™ inhibits microbial colonization and suppresses microbial regrowth under the dressing.

Warnings

SurgiClear™ SHOULD NOT BE USED AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.

SurgiClear™ SHOULD NOT BE USED ON THIRD DEGREE BURNS.

SurgiClear™ SHOULD NOT BE USED ON PREMATURE INFANTS OR INFANTS YOUNGER THAN 2 MONTHS OF AGE. USE OF SurgiClear™ ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN.

SurgiClear™ SHOULD NOT BE USED AS THE PRIMARY MEANS TO FIX ARTERIAL CATHETERS OR ARTERIAL CANNULAE.

SurgiClear™ IS FOR EXTERNAL USE ONLY AND SHOULD NOT BE ALLOWED TO CONTACT EARS, EYES, MOUTH OR MUCOUS MEMBRANES.

SurgiClear™ CONTAINS SILVER AND MAY CAUSE IMAGE ARTIFACTS IN MRI SCANS.

SurgiClear™ SHOULD NOT BE USED ON PATIENTS WITH KNOWN HYPERSENSITIVITY OR ALLERGY TO SILVER.

SurgiClear™ SHOULD NOT BE USED ON PATIENTS WITH KNOWN HYPERSENSITIVITY OR ALLERGY TO CHLORHEXIDINE. THE USE OF CHLORHEXIDINE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION AND GENERALIZED ALLERGIC REACTIONS. Hypersensitivity reactions associated with topical use of chlorhexidine have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing chlorhexidine, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the U.S.A. under any circumstances. Caution should be used when using chlorhexidine containing preparations, and the patient should be observed for possibilty of hypersensitivity reactions.

IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Precautions

SurgiClear™ is not intended to treat catheter-related blood stream infections (CRBSI) or other percutaneous device-related infections and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Hemostasis of any insertion site should be achieved before applying the dressing.

The dressing should not be stretched during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Active Ingredients

Chlorhexidine and Silver reduce the incidence of bacterial colonization under the entire dressing.

Directions for use

Prepare the site as protocol dictates. Open the sterile SurgiClear™ pouch and remove the dressing.

Application:

1. Remove the centre window of the paper backing.
2. Hold the flap of the top blue liner and peel off. Place the exposed adhesive on the skin and smooth the dressing over the skin.
3. Hold the flap of the remaining blue liner and peel off and smooth the dressing over the skin towards the edges.
4. To remove frame; start from the pre-cut line, peel off in a circular motion and smooth the dressing towards the edges to ensure good adhesion.

Site Care:

1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.
2. Inspect the dressing daily and change the dressing as necessary, in accordance with facility protocol. Dressing changes should occur at least every 7 days and may be needed more frequently with highly exudative sites if integrity of the dressing is compromised.
3. The dressing should be changed as necessary:
   - If the dressing becomes loose, soiled or compromised in any way
   - If the site is obscured or no longer visible
   - If there is visible drainage

   Note: SurgiClear™ is not designed to absorb blood or fluid.

Dressing Removal

Change dressing as good nursing practices dictate. To remove the dressing, gently lift one edge of the dressing and slowly peel away.

Storage Information and Shelf Life

- The dressing should be stored in a cool, dry place (≤25°C/75°F).
- Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier until the expiration date printed on the package.
- The expiration date of SurgiClear™ is provided on the package.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured in the USA for: Covalon Technologies Inc., Mississauga (Ontario) L4Z 3E6 Canada
www.covalon.com

™ trademark of Covalon Technologies.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

covalon

SurgiClear[MC]

Pansement adhésif antimicrobien en silicone transparent à la chlorhexidine et à l'argent

MODE D'EMPLOI

Description

SurgiClear[MC] est un pansement adhésif antimicrobien en silicone transparent à la chlorhexidine et à l'argent utilisé pour couvrir et protéger les sites de plaie et les dispositifs de fermeture de plaie. SurgiClear[MC] fixe également les pansements primaires à la peau. Le pansement se compose d'un film transparent de polyuréthane enduit d'un adhésif antimicrobien en silicone contenant de la chlorhexidine à 3 % M/M et des sels d'argent à 0,5 % M/M. L'adhésif antimicrobien en silicone de SurgiClear réduit l'incidence d'arrachement de la couche épidermique et est jusqu'à dix fois moins douloureux à l'enlèvement que les pansements contenant des adhésifs acryliques.

SurgiClear[MC] fournit une barrière efficace contre les contaminants externes, y compris les liquides (étanche), les bactéries et les levures. La chlorhexidine et l'argent incorporés dans l'adhésif en silicone assurent une activité antimicrobienne continue tout au long de la période de port recommandée contre un éventail de bactéries Gram-positives et Gram-négatives et contre la levure, dont *Staphylococcus aureus* (SARM), *Staphylococcus epidermidis*, *Enterococcus faecalis* (ERV), *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Enterobacter cloacae*, *Candida albicans* et *Candida tropicalis*.

SurgiClear[MC] est un film transparent qui permet de surveiller et d'évaluer constamment le site ou la plaie. Le pansement est auto-adhésif et respirable, ce qui permet un bon échange de la vapeur d'eau.

Indications

SurgiClear[MC] est destiné à couvrir et protéger les sites de plaie contre la contamination externe, y compris les plaies postopératoires, débridées ou d'épaisseur partielle, telles que les sites donneurs de greffe de peau, les abrasions, les lacérations, les déchirures cutanées, les brûlures au premier et au deuxième degré.

Le pansement SurgiClear[MC] peut être utilisé pour couvrir et protéger les dispositifs de fermeture de plaie (à savoir les sutures, les agrafes, les clips), les broches orthopédiques, les dispositifs de fixation et les fils ainsi que les drains. SurgiClear[MC] peut également être utilisé pour couvrir et fixer les pansements primaires.

SurgiClear[MC] inhibe la colonisation microbienne et empêche sa revivification sous le pansement.

Avertissements

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ COMME REMPLACEMENT DE SUTURES ET AUTRES MÉTHODES PRIMAIRES DE FERMETURE DE PLAIE.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES BRÛLURES AU TROISIÈME DEGRÉ.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES NOURRISSONS PRÉMATURÉS OU LES NOURRISSONS ÂGÉS DE MOINS DE 2 MOIS. SON UTILISATION SUR DES NOURRISSONS PRÉMATURÉS PEUT ENTRAÎNER DES RÉACTIONS D'HYPERSENSIBILITÉ OU LA NÉCROSE DE LA PEAU.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ COMME MOYEN PRIMAIRE DE FIXER DES CATHÉTERS ARTÉRIELS OU DES CANULES ARTÉRIELLES.

SurgiClear[MC] EST DESTINÉ À UN USAGE EXTERNE UNIQUEMENT ET NE DOIT PAS ÊTRE AUTORISÉ À ENTRER EN CONTACT AVEC LES OREILLES, LES YEUX, LA BOUCHE OU LES MUQUEUSES.

CE PANSEMENT CONTIENT DE L'ARGENT ET PEUVENT PROVOQUER DES IMAGES EN IRM.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES PATIENTS PRÉSENTANT UNE HYPERSENSIBILITÉ OU UNE ALLERGIE CONNUE À L'ARGENT.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES PATIENTS PRÉSENTANT UNE HYPERSENSIBILITÉ OU UNE ALLERGIE CONNUE À LA CHLORHEXIDINE. L'UTILISATION DE PRODUITS CONTENANT DE LA CHLORHEXIDINE A ÉTÉ SIGNALÉE COMME PROVOQUANT DES IRRITATIONS, UNE SENSIBILISATION ET DES RÉACTIONS ALLERGIQUES GÉNÉRALISÉES. Des réactions d'hypersensibilité associées à l'utilisation topique de chlorhexidine ont été signalées dans plusieurs pays. Les réactions les plus graves (y compris l'anaphylaxie) ont été observées chez des patients traités avec des lubrifiants contenant de la chlorhexidine, utilisés lors d'interventions sur le tractus urinaire. Les préparations de ce type ne sont pas approuvées pour la vente aux États-Unis, quelles que soient les circonstances. La prudence est de mise lors de l'utilisation de préparations contenant de la chlorhexidine, et le patient doit être surveillé afin de délecter toute réaction éventuelle d'hypersensibilité.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or call 301-796-8118.

SI DES RÉACTIONS ALLERGIQUES SE PRODUISENT, CESSEZ IMMÉDIATEMENT L'UTILISATION. EN PRÉSENCE D'UNE RÉACTION GRAVE, CONTACTEZ UN MÉDECIN.

Précautions

Le pansement SurgiClear[MC] n'est pas destiné à traiter les infections sanguines causées par les cathéters (CRBSI), ni les autres infections causées par les dispositifs percutanés. De plus, le pansement n'a pas fait l'objet d'une étude clinique randomisée quant à son efficacité dans la prévention de telles infections.

L'hémostase de tout site d'insertion doit être réalisée avant d'appliquer le pansement.

Le pansement ne doit pas être étiré lors de l'application. Un traumatisme mécanique de la peau peut se produire si le pansement est apposé en appliquant une tension.

La peau doit être sèche et exempte de résidus de détergent pour prévenir une irritation cutanée et assurer une bonne adhérence. Laissez sécher complètement tous les produits de préparation et de protection avant d'appliquer le pansement pour éviter des irritations de la peau et pour assurer une bonne adhérence.

Ingrédients actifs

La chlorhexidine et l'argent réduisent l'incidence de colonisation bactérienne sous l'ensemble du pansement.

Mode d'emploi

Préparez le site selon les exigences du protocole. Ouvrez le sachet stérile SurgiClear[MC] et retirez le pansement.

Application:

1. Soulever la fenêtre centrale du support papier.
2. Tirez l'aileron du revêtement bleu supérieur et épluchez. Placez l'adhésif exposé sur la peau et lissez le habillage au-dessus de la peau.
3. Tirez le rabat du revêtement bleu restant et retirez-le.
4. Pour enlever le contour; débuter à la ligne prédécoupée; décoller d'un mouvement circulaire et lisser le pansement vers les côtés afin d'assurer une bonne adhérence.

Soins du site:

1. Observez le site chaque jour à la recherche de signes d'infection ou autres complications. Si une infection est soupçonnée, retirez le pansement, inspectez le site directement et déterminez l'intervention médicale appropriée. L'infection peut se manifester par une fièvre, une douleur, une rougeur, une enflure, ou une odeur ou un écoulement inhabituel.
2. Inspectez le pansement chaque jour et changez-le au besoin, conformément au protocole de l'établissement. Les pansements doivent être changés au moins tous les sept (7) jours et peuvent nécessiter d'être changés plus souvent en présence d'une haute quantité d'exsudat si l'intégrité du pansement est compromise.
3. Le pansement doit être changé au besoin:
   - s'il est lâche, sali ou compromis de quelque manière que ce soit;
   - si le site est obscurci ou n'est plus visible;
   - en présence d'un drainage visible.

Remarque: SurgiClear[MC] n'est pas conçu pour absorber le sang ou les liquides.

Enlèvement du pansement

Changez le pansement conformément aux bonnes pratiques des soins infirmiers. Pour enlever le pansement, soulevez délicatement un bord du pansement puis décollez-le lentement.

Informations d'entreposage et durée de conservation

- Le pansement doit être entreposé dans un endroit frais et sec (à une température inférieure ou égale à 25°C/75°F).
- À condition que l'intégrité de l'emballage ne soit compromise d'aucune façon, l'emballage formera une barrière efficace jusqu'à la date de péremption imprimée sur l'emballage.
- La date de péremption du pansement antimicrobien SurgiClear[MC] est indiquée sur l'emballage.

ATTENTION : La loi fédérale (des États-Unis) n'autorise la vente de ce dispositif que par un médecin ou sur son ordonnance.

Fabriqué aux États-Unis pour: Covalon Technologies Inc., Mississauga (Ontario) L4Z 3E6 Canada www.covalon.com

[MC] Marque de commerce déposée de Covalon Technologies

Product availability / Disponibilité du produit

Product Description / Description du produit	Code	Size / Taille	Box / Boîte
SurgiClear™ (with crosshair) (avec fils croisés)	TWBD1021	4cm x 4cm (1½in x 1½in) / (1½po x 1½po)	25 pouches per carton / sachets par carton
SurgiClear™	TWBD1022	4cm x 4cm (1½in x 1½in) / (1½po x 1½po)	
SurgiClear™	TWBD1017	4cm x 7cm (1½in x 2¾in) / (1½po x 2¾po)	
SurgiClear™	TWBD1018	4cm x 13cm (1½in x 5⅛in) / (1½po x 5⅛po)	
SurgiClear™	TWBD1019	10cm x 12cm (4in x 4¾in) / (4po x 4¾po)	
SurgiClear™	TWBD1023	6cm x 20cm (2⅜in x 8in) / (2⅜po x 8po)	
SurgiClear™	TWBD1024	6cm x 25cm (2⅜in x 10in) / (2⅜po x 10po)	
SurgiClear™	TWBD1025	6cm x 30cm (2⅜in x 12in) / (2⅜po x 12po)	

Not made with natural rubber latex. Sterile unless opened or damaged.
Non fait de latex de caoutchouc naturel. Stérile à moins d'être ouvert ou endommagé.

This is a single use device and should not be re-sterilized.

Ceci est un dispositif à usage unique et il ne doit pas être restérilisé.



LS-044-2
(ROW)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-OSTATUS@fda.hhs.gov or call 301-796-8118.
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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Attachment 13.9
Predicate, SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidene and Silver- Marketing Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

SurgiClear™

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

- ✓ Dual antimicrobials with the synergystic effect of chlorhexidine and silver[1] - proven to kill 99.99% of microorganisms most commonly associated with SSI and prevent their regrowth for up to 7 days[2]
- ✓ Clear, breathable and a waterproof barrier against external contamination[3]
- ✓ Soft silicone adhesive technology protects fragile skin and minimizes pain and trauma during dressing changes[3, 4-11]



CONVENIENT

- 2 piece liner and tabbed paper frame for easy application
- Window delivery for increased positioning accuracy
- Transparency allows for continuous visualization of the area
- Easy to apply and use, conforms well to body contours of multiple site areas

ANTIMICROBIAL PROTECTION

- Transparent and breathable film with dual antimicrobials chlorhexidine and silver, embedded in the soft silicone adhesive
- Provides antimicrobial protection throughout the entire surface area for up to seven days[2]
- Dual antimicrobials kill 99.99% of bacteria and yeast commonly associated with SSIs[2]
- Antimicrobial effect sustained under the full surface area of the dressing[2]

SOFT SILICONE ADHESIVE

- Allows visibility of the incision site
- Highly flexible over joints
- Non sensitizing, reduces pain and trauma at dressing change[2 4 11]
- Leaves no residue and is easy to remove
- Highly breathable, constantly transfers excess moisture[13]

EXTERNAL PROTECTION

- Barrier to external contamination[2]
- Fluid impermeable and waterproof[13]

HOW DOES IT WORK?

SurgiClear™ has two antimicrobials – chlorhexidine and silver embedded in the soft silicone adhesive, allowing for optimized protection over the entire surface area.

ial standards

ormance.

on gram positive and gram negative bacteria and yeast commonly associated with Surgical Site Infections (SSI)*. The soft silicone adhesive used for SurgiClear™ minimizes pain to patients and trauma to wounds.



SurgiClear™

al Clear Silicone Adhesive Dressings

055 | surgiclear@covalon.com

covalon TECHNOLOGIES LTD.

SurgiClear is a trademark of Cov

DA/CDRH/OCE/DID at CDRH-FOISTAT@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

SurgiClear™

AREAS OF 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 dressings
- SurgiClear™ inhibits microbial growth within the dressing and prevents external contamination[1,2, 12]

SITE PREPARATION

- Read precautions and warnings in package insert prior to use
- Prepare the site according to your facility's protocol
- Clipping hair at the site may improve dressing adhesion
- Allow all aseptic preparations to dry completely before applying SurgiClear™ to ensure good adhesion

HOW TO APPLY

1. Open the package and remove the sterile SurgiClear™ dressing. Remove the white paper window panel such that only a frame of white paper remains.
2. Peel the larger blue liner to expose the adhesive. Place the dressing adhesive side down, ensuring that the incision will be covered. Smooth the dressing over the skin towards the edges to ensure good adhesion.
3. Remove second blue liner while continuously smoothing with opposite hand.
4. Starting at the pre-cut slit in the frame slowly remove paper frame while applying firm but gentle pressure along the edges of the dressing.


1.


2.


3.


4.

NOTE: As with any medical device, always refer to the full .

FREQUENCY OF CHANGE

SurgiClear™ provides antimicrobial dressing protection for up to seven days, and will remain in place depending on the condition of the site.

CARE AND REMOVAL

- Inspect the dressing daily and change the dressing as per facility protocol
- SurgiClear™ should be changed as necessary if it becomes loose
- Use universal precautions as indicated by established protocol for infection prevention. If infection is suspected, remove the dressing and determine the appropriate medical intervention
- To remove, simply peel SurgiClear™ off slowly supporting any other devices to minimize the risk of dislodgement
- No additional swabbing or cleaning is required

AVAILABILITY

Reference Number	Size (in/cm)	Dressings per Carton	Cartons per Case	HCPCS
TWBD1022	1.5in x 1.5in 4cm x 4cm	25	4	A6257
TWBD1017	1.5in x 2.8in 4cm x 7cm	25	4	A6257
TWBD1018	1.5in x 5in 4cm x 13cm	25	4	A6257
TWBD1019	4in x 4.8in 10cm x 12cm	25	4	A6258
TWBD1023	2.5in x 8in 6cm x 20cm	25	4	A6258
TWBD1024	2.5in x 10in 6cm x 25cm	25	4	A6258
TWBD1025	2.5in x 12in 6cm x 30cm	25	4	A6258

REFERENCES: 1. Blom K Werthen M A Laboratory Study of the Synergistic Effect of Chlorhexidine and Silver Poster Publication Wound UK 2014 **2.** DiTizio V Romano M A Novel Antimicrobial Clear Silicone Dressing with Chlorhexidine and Silver Poster Publication Association for Vascular Access Annual Scientific Meeting San Antonio USA 2012 **3.** Hydrostatic Pressure GLP Report Nelson Laboratories 2012 **4.** White R A multinational survey of the assessment of pain when removing dressings Wounds UK 2008 **5.** White R Evidence for atraumatic soft silicone wound dressing use Wounds UK 2005 **6.** Meaume S et al A study to compare a new self adherent soft silicone dressing with a self adherent polymer Ostomy Wound Management 2003 **7.** Wiberg A B et al Preventing maceration with a soft silicone dressing in vitro evaluations Poster publication WUWHS congress Canada 2008 **8.** Dykes P J et al Effect of adhesive dressings on the stratum corneum of the skin Journal of Wound Care 2001 **9.** Waring M et al An evaluation of the skin stripping of wound dressing adhesives Journal of Wound Care 2011 **10.** Feili F et al Retention capacity Poster publication EWMA conference Lisbon Portugal 2008 **11.** Hedgepeth N et al Clinical Performance of a New Clear Silicone Adhesive Dressing with Chlorhexidine and Silver for Central Vascular Access Devices (VADs) Wearability Comfort and Incidence of Irritant Contact Dermatitis Poster Publication SAWC Fall Las Vegas USA 2014 **12.** Blom K Werthen M In Vitro Study of the Efficacy of a Novel Antimicrobial Dressing with Soft Silicone Adhesive in a Diffusion Model Mimicking a Catheter Insertion Site Poster Publication at SAWC Spring 2015 San Antonio USA **13.** Covalon Technologies Ltd Data on file



SurgiClear™

al Clear Silicone Adhesive Dressings

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SurgiClear™ and IV Clear™ by Covalon Technologies Ltd. distributed by TissueSeal

TissueSeal™

Superior dual-antimicrobial protection. Where it's needed most.

With infection rates on the rise, the cost of using the wrong dressing is growing by the day. **SurgiClear**™ and **IV Clear**™ offer a solution not found anywhere else. By combining 2 powerful antimicrobials in a breathable, liquid-resistant silicone dressing, **SurgiClear**™ and **IV Clear**™ give you unmatched 7-day bacteria-fighting performance.*

2 GOLD-STANDARD ANTIMICROBIAL AGENTS

The synergy of chlorhexidine and silver provides a broader spectrum of antimicrobial protection and an effective barrier against external contamination.

PROVEN 7-DAY PERFORMANCE

Superior suppression of microorganisms with a greater-than-4-log reduction over a 7-day wear period.*

99.99% MICROBIAL REDUCTION

Meets or exceeds the FDA's guidance requiring at least a 99.99% microbial reduction on a 6-log inoculation during testing.*

CLEAR EVALUATION

Patented photo-stabilization technology inhibits silver from discoloring for a full 7 days of transparency. This enables continuous site assessment, and prevents unnecessary dressing removal.

GREATER COMFORT

Soft, breathable silicone adhesive and polyurethane film provide optimal oxygen and moisture exchange to help avoid skin maceration and offer greater patient comfort.

PAIN-FREE REMOVAL

Silicone adhesive is up to 10 times less painful to remove than acrylic adhesives.



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7-day Bacteria-Fighting Performance

Contact

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734-213-5536
info@tissueseal.com
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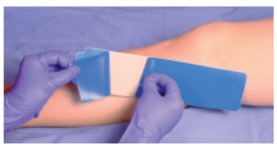
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How and when to use **SurgiClear**™

SurgiClear™ covers and protects wound sites and wound closure devices, and can also secure primary dressings to the skin. SurgiClear™ covers and protects wound sites against external contamination, including:







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- **Post-operative, debrided or partial thickness wounds**
- **Skin graft donor sites**
- **Abrasions**
- **Lacerations**
- **Skin tears**
- **First and second degree burns**

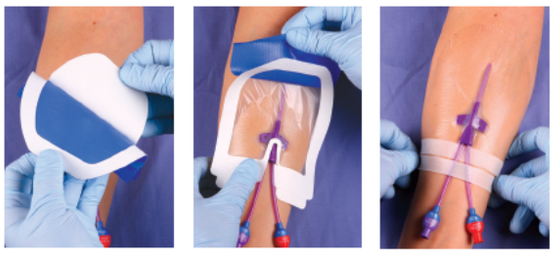
PRODUCT DESCRIPTION	SIZE	BOX	CODE
SurgiClear™	4cm x 4cm (1½ in x 1½ in)	25 dressings	TWBD1022
SurgiClear™	4cm x 7cm (1½ in x 2¾ in)	25 dressings	TWBD1017
SurgiClear™	4cm x 13cm (1½ in x 5⅛ in)	25 dressings	TWBD1018
SurgiClear™	10cm x 12cm (4 in x 4¾ in)	25 dressings	TWBD1019
SurgiClear™	6cm x 20cm (2½ in x 8 in)	25 dressings	TWDB1023
SurgiClear™	6cm x 25cm (2½ in x 10 in)	25 dressings	TWDB1024
SurgiClear™	6cm x 30cm (2½ in x 12 in)	25 dressings	TWDB1025

Not intended as a substitute for instructions for use (IFU). Read full IFU prior to use.

How and when to use **IV Clear**™

IV Clear™ covers and protects insertion sites, and secures devices to skin, including:

- **IV catheters**
- **Central venous lines**
- **PICCs**
- **Suction catheters**
- **Epidural catheters**
- **Hemodialysis**
- **Catheters**
- **Orthopedic pins**



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PRODUCT DESCRIPTION	SIZE	BOX	CODE
IV Clear™	4cm x 4cm (1½ in x 1½ in)	25 dressings	TWBD1011
IV Clear™	6cm x 7cm (2⅜ in x 2¾ in)	25 dressings	TWBD1020
IV Clear™	10cm x 12cm (4 in x 4¾ in)	25 dressings	TWBD1014

Not intended as a substitute for instructions for use (IFU). Read full IFU prior to use.

Contact

For more detailed information,
call: **877-754-6458** or **734-213-5536**
email: **info@tissueseal.com**
fax: **734-213-5640**
visit: **tissueseal.com**

TissueSeal™

TissueSeal, LLC
5643 Plymouth Rd.
Ann Arbor, MI 48105

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Bacteria Basics in Skin Prep

Experts share the things surgical teams miss.

By Rebecca Rudolph-Witt, editor



(Courtesy of the Association of periOperative Registered Nurses)

Reducing surgical site infections (SSIs) and healthcare associated infections (HAIs) has always been a challenge in healthcare. Although new technology has helped reduce risk for some areas of medicine, the elusive SSI is still a reality for one in three surgery patients. To find where these bacteria hide, *Surgical Products* connected with the infection experts.

How has research created awareness to the bacteria patients bring into the surgery on their skin?

Dr. J. Hudson Garrett Jr., PhD, MSN, MPH, FNP-BC, CSRN, PLNC, VA-BC, vice president of clinical affairs at PDI, Inc.: Current research continues to highlight the role of the patient's own skin in contributing to the risk for the development of SSIs. The human skin serves as a natural barrier to infection when it is intact, however during surgery, the skin is compromised, which can allow currently present pathogenic flora to enter the surgical site and cause SSI. This risk factor is a fundamental reason why preoperative skin cleansing prior to the surgical procedure can be helpful in reducing the risk for SSI.

Although new technology has helped reduce risk for some areas of medicine, the elusive SSI is still a reality for one in three surgery patients.

The medical profession continues to recognize the significant impact of SSIs to the patient, as well as the associated mortality and morbidity. The use of preoperative

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bathing to cleanse the skin is well accepted and supported in the clinical literature and evidence based clinical guidelines.

Where do bacteria commonly hide on patients?

Garrett: Bacteria are found everywhere on the human skin, and most bacteria serve an essential function to protect us from infection. The most heavily colonized area on the human body is typically the groin due to the skin folds, moisture-rich environment, and hair follicles. This site is very difficult to perform adequate antisepsis on as well. Other heavily colonized areas can include the rectum and abdomen.

Caroline Johnson, BSN, RN, a technical service specialist at 3M Infection Prevention Division: Many facilities may have a preoperative antiseptic bathing protocol in place, but bacteria found in other reservoirs such as the nose may be overlooked. *Staphylococcus aureus* is the leading cause of SSI and is commonly found on the skin and also present in the nose in approximately 30 percent of the population. Nasal colonization with *S. aureus* is a well-documented risk factor for infection and reducing bacteria present in the nose can help reduce SSI risk.

"The human skin serves as a natural barrier to infection when it is intact, however during surgery, the skin is compromised, which can allow currently present pathogenic flora to enter the surgical site and cause a SSI."
Dr. J. Hudson Garret Jr.

What methods are currently available to prep patients for surgery?

Garrett: There are many antiseptic formulations available to perform skin antisepsis prior to surgery. Currently available solutions include alcohol, PVP iodine and Chlorhexidine containing antiseptics. The majority of facilities use a Chlorhexidine gluconate containing solution that is easily applied to the patient's skin and has the synergistic effect of Chlorhexidine gluconate and Isopropyl Alcohol.

Johnson: Effectively reducing bacteria and achieving persistence in the nose to reduce infection risk can be challenging because the nose is a unique and complex environment that is much different than that of the skin. Historically, a topical antibiotic ointment has been used to prior to surgery, but requires patients to complete an outpatient dosing regimen. This strategy is reliant upon patient compliance, which can be difficult to validate, instead of putting control in the hands of the healthcare provider.

How can surgical teams make sure patients are complying with patient prep procedures?

Garrett: Patient education is critical to ensuring the success of a preoperative skin cleansing that is performed by the patient. Patients must be fully aware of the importance of adherence to the process and technology should be utilized to improve compliance. There are new capabilities to send the patient text and email reminders to perform the procedure and be compliant with the preoperative instructions provided by the surgeon. SP

Can your post-op dressing;

Kill 99.99% of microorganisms?*
Offer total incision site visibility?
Eliminate adhesive skin injuries?



SurgiClear™
Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

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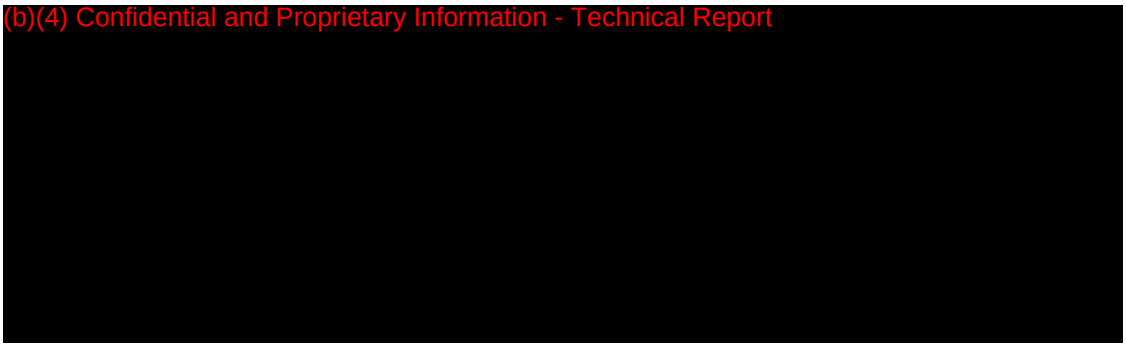
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Section 14- Sterilization Validation and Shelf Life

Sterilization Summary

The finished device, the ReliaTect™ Post-Op Dressing with CHG, will be sold in a sterile state. The dressings will be sterilized (b) (4), a contract sterilizer.

Sterilization Method: (b) (4)
Dose: (b) (4)
Validation Method: (b) (4)
Sterility Assurance Level (SAL): 10^{-6}

A protocol for substantiation of a minimum sterilization dose of (b) (4) was executed to ensure the cycle would achieve a Sterility Assurance Level (SAL) of 10^{-6}. (b) (4)
(b)(4) Confidential and Proprietary Information

Packaging

The ReliaTect™ Post-Op Dressings are individually packaged into a (b) (4)
(b)(4) Confidential and Proprietary Information The pouch is comprised of (b) (4)
(b)(4) Confidential and Proprietary Information
(b) (4) The properties of the packaging are tested throughout
(b)(4) Confidential and Proprietary Information

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Shelf Life Summary

An expiration date is needed in order to provide a time period during which the device may be used thus product performance is assessed at various time intervals. The performance characteristics of the ReliaTect™ Post-Op Dressing with CHG were evaluated against the required specifications.(b)(4) Confidential and Proprietary Information

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Table 14.1
Comparison Diagrams, MED 9807S and the ReliaTect™ Post-Op Dressings with CHG

ReliaTect™ Post-Op Dressing with CHG		(b) (4)

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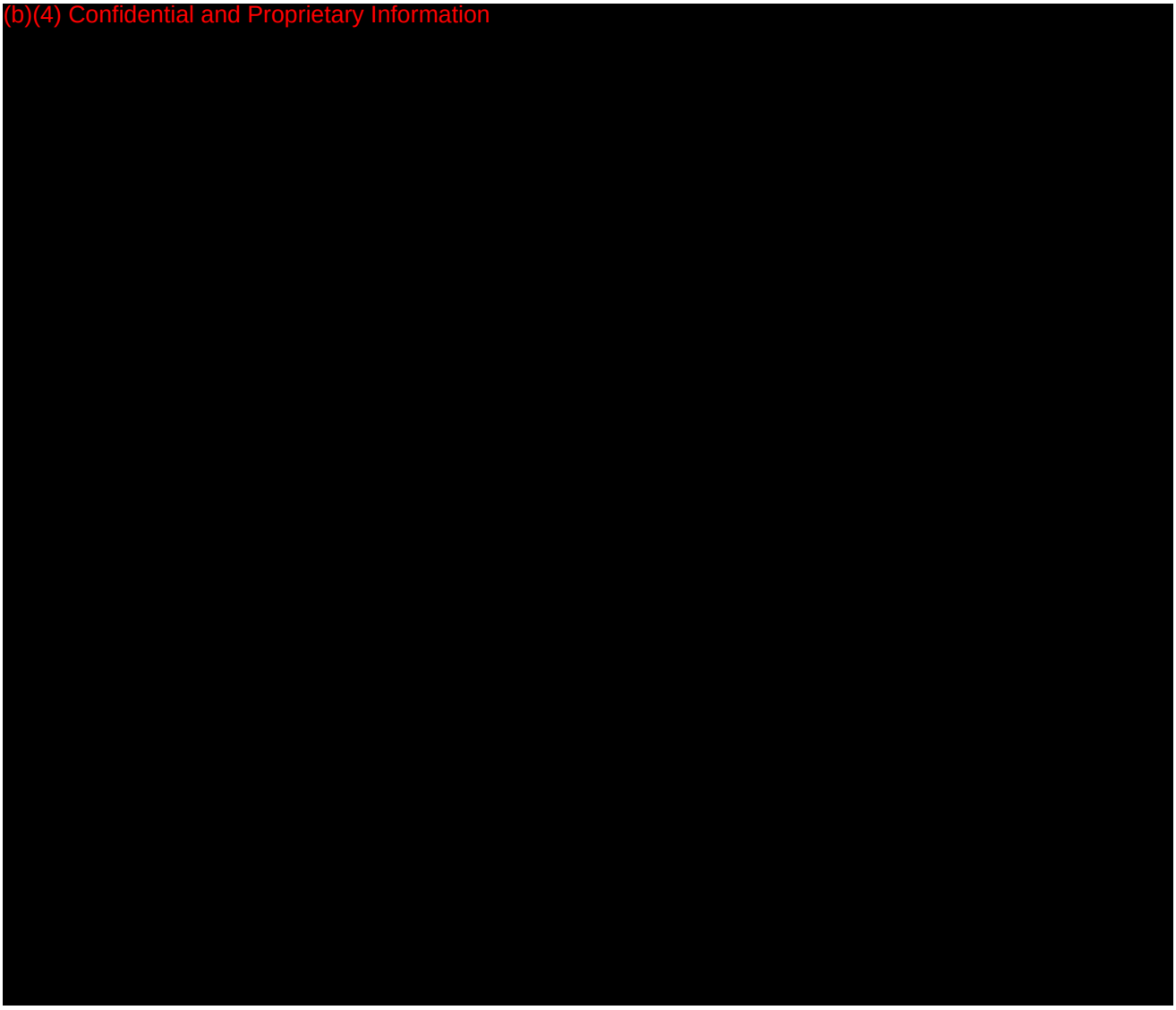
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Conclusion

Based on the data obtained for (b)(4) Confidential and Proprietary Information (b) (4) a shelf life of (b) (4) has been determined for the ReliaTect™ Post-Op Dressings with CHG.

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Attachment 14.1
Sterilization Validation Protocol

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Section 15- Biocompatibility

Avery Dennison België BVBA received clearance for its Benehold™ IV dressing containing CHG in 2012 (K113836). (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

The ReliaTect™ Post Op Dressing with CHG has been evaluated for biocompatibility according to ISO 10993 to determine if there are any biological risks that may arise from the use of the device as intended. This section will summarize the overall biocompatibility of the proposed device and subsequently describe the activities and approach taken to support the biocompatibility summary.

Test Methodology:

According to ISO 10993-1 categorization, the ReliaTect™ Post Op Dressing with CHG is categorized (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 15.1

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

A summary of the biocompatibility testing is provided in Table 15.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Table 15.2 (b) (4)			
Test	Method	Results	Attachment
Cytotoxicity	(b)(4) Confidential and Proprietary Information ISO 10993-5: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	(b)(4) Confidential and Proprietary Information	
Sensitization	(b) (4) ISO 10993-10: Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization		
Irritation	(b)(4) Confidential and Proprietary Information ISO 10993-10: Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization		

(b)(4) Confidential and Proprietary Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

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Summary

The ReliaTect™ Post Op Dressings with CHG met the biocompatibility requirements set forth within ISO 10993-1 (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b) (4) [redacted] safety or effectiveness of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Attachment 15.1
Cytotoxicity Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Cytotoxicity Report

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Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Section 16- Software

This section is not applicable since the ReliaTect™ Post-Op Dressing with CHG does not contain any software.

Questions? Contact FDA/CDRH at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Section 17- Electromagnetic Compatibility and Electrical Safety

This section is not applicable since The ReliaTect™ Post-Op Dressing with CHG is not an electronic device and therefore not subjected to electromagnetic forces.

Questions? Contact FDA/CDRH at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2017-7363; Released by CDRH on 09-10-18.

Section 18 – Performance Testing, Bench

This section describes the performance testing completed for the ReliaTect™ Post-Op Dressing with CHG. Testing of the ReliaTect™ Post-Op Dressing with CHG was performed to ensure that the dressing meets design requirements. Table 18.1 summarizes (b)(4) Confidential and Proprietary Information

Table 18.1

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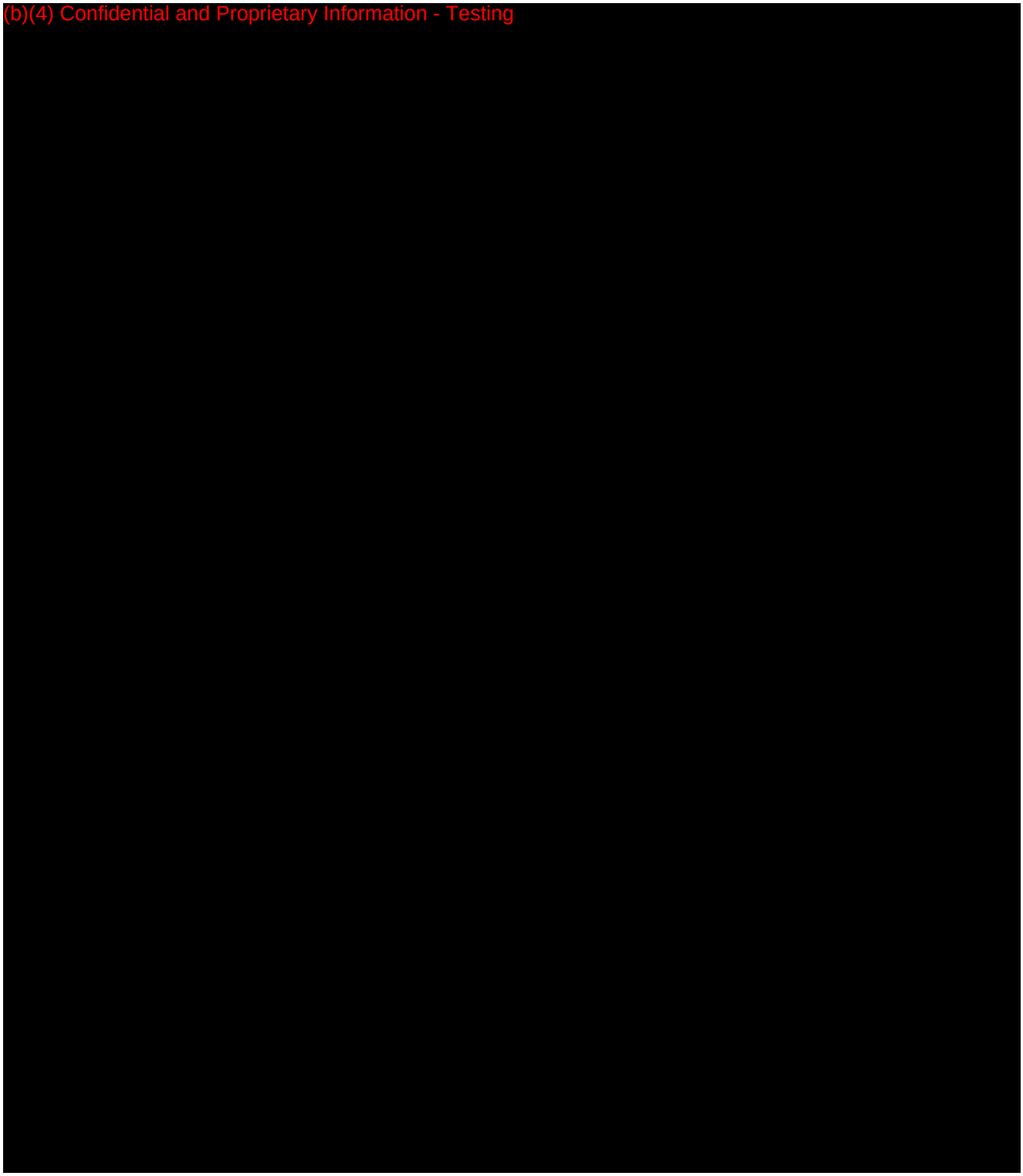
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Section 19: Performance Testing - Animal

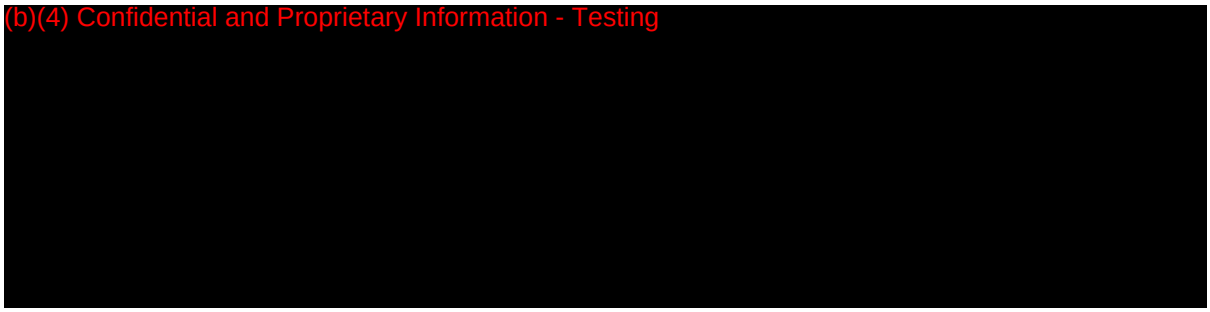
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section 20- Performance Testing- Clinical

This section is not applicable, since there were no Clinical Trials for The ReliaTect™ Post-Op Dressing with CHG.

Questions? Contact FDA/CDRH at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Traditional 510(k) Premarket Notification
ReliaTect™ Post-Op Dressing with CHG

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(b)(4) Confidential and Proprietary Information

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Questions? Contact FDA/CDRH/OGE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OGE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K163529/S001

AVERY DENNISON

7100 Lindsay Drive
Mentor, Ohio 44060
Phone: (440) 358-2600
Fax: (440) 358-2895

February 20, 2017

FDA/CDRH/DCC
FEB 23 2017
RECEIVED

Mr. Charles Durfor
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Avery Dennison 510(k) Application K163529
Device: ReliaTect Post-Op Dressing with CHG

Dear Mr. Durfor,

We have reviewed your request for additional information regarding the Traditional 510(k) submission for the ReliaTect Post-Op Dressing with CHG (reference K163529) and have provided detailed responses to each of your points below. Based upon your requests, we are enclosing the required data to complete review of our submission. Avery Dennison is submitting two copies of the response to the Hold Letter for K163529 issued on February 10, 2017. An electronic copy of the submission is provided to facilitate the review. The eCopy is an exact duplicate of the paper copy. If you need any further information, please direct such correspondence to me at the e-mail address or telephone number provided below. Thank you.

Best Regards,

(b) (6) [redacted]

Lisa Bartakovics
Director of Global Regulatory Affairs
Avery Dennison Corporation
T: 312-206-6159 e-mail: Lisa.Bartakovics@averydennison.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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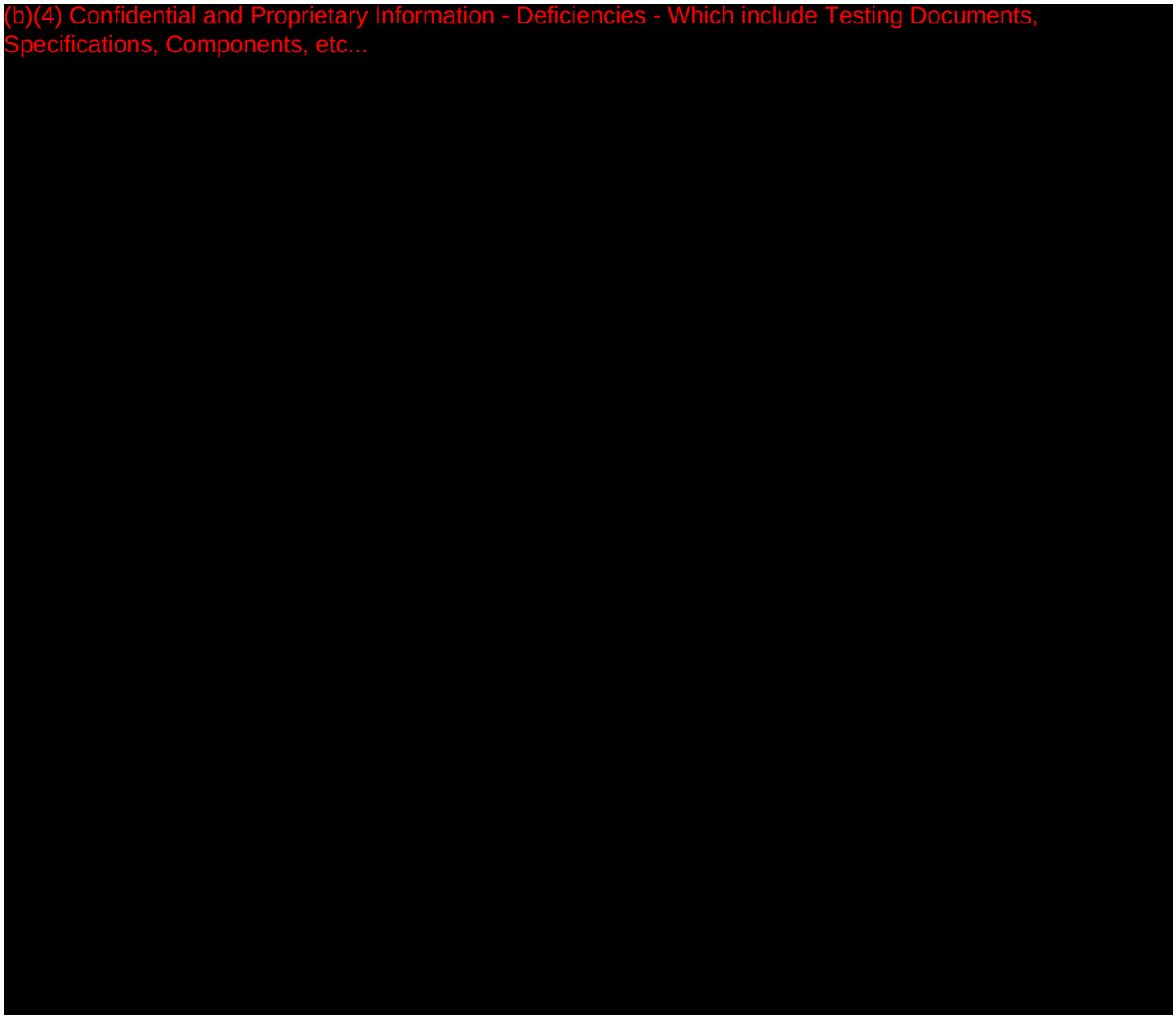
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Attachment 3.2
Revised 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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.

Questions? Contact FDA/CDRH/OCE/DID at PDRU-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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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 was performed and supports *in vitro* antimicrobial performance of the ReliaTect™ Post-Op Dressing with CHG.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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covalon

SurgiClear™

Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver

INSTRUCTIONS FOR USE

Description

SurgiClear™ is an Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver used to cover and protect wound sites and wound closure devices. SurgiClear™ also secures primary dressings to skin. The dressing consists of a clear polyurethane film coated with an antimicrobial silicone adhesive containing 3% w/w chlorhexidine and 0.5% w/w silver salts. SurgiClear's antimicrobial silicone adhesive reduces incidence of epidermal stripping and is up to ten times less painful upon removal compared to dressings containing acrylic adhesives.

SurgiClear™ provides an effective barrier against external contamination including fluids (waterproof), bacteria, and yeast. The chlorhexidine and silver incorporated within the silicone adhesive provides continuous antimicrobial activity over the recommended wear time against a variety of gram positive bacteria, gram negative bacteria and yeast, including *Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Enterococcus faecalis (VRE), Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter cloacae, Candida albicans*, and *Candida tropicalis*.

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.

Indications for Use

SurgiClear™ is intended to cover and protect wound sites, against external contamination, including post-operative, debrided or partial thickness wounds such as skin graft donor sites, abrasions, lacerations, skin tears, first and second degree burns.

SurgiClear™ can be used to cover and protect wound closure devices (i.e. sutures, staples, clips), orthopedic pins, fixtures and wires as well as drains. SurgiClear™ may also be used to cover and secure primary dressings.

SurgiClear™ inhibits microbial colonization and suppresses microbial regrowth under the dressing.

Warnings

SurgiClear™ SHOULD NOT BE USED AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.

SurgiClear™ SHOULD NOT BE USED ON THIRD DEGREE BURNS.

SurgiClear™ SHOULD NOT BE USED ON PREMATURE INFANTS OR INFANTS YOUNGER THAN 2 MONTHS OF AGE. USE OF SurgiClear™ ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN.

SurgiClear™ SHOULD NOT BE USED AS THE PRIMARY MEANS TO FIX ARTERIAL CATHETERS OR ARTERIAL CANNULAE.

SurgiClear™ IS FOR EXTERNAL USE ONLY AND SHOULD NOT BE ALLOWED TO CONTACT EARS, EYES, MOUTH OR MUCOUS MEMBRANES.

SurgiClear™ CONTAINS SILVER AND MAY CAUSE IMAGE ARTIFACTS IN MRI SCANS.

SurgiClear™ SHOULD NOT BE USED ON PATIENTS WITH KNOWN HYPERSENSITIVITY OR ALLERGY TO SILVER.

SurgiClear™ SHOULD NOT BE USED ON PATIENTS WITH KNOWN HYPERSENSITIVITY OR ALLERGY TO CHLORHEXIDINE. THE USE OF CHLORHEXIDINE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION AND GENERALIZED ALLERGIC REACTIONS. Hypersensitivity reactions associated with topical use of chlorhexidine have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing chlorhexidine, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the U.S.A. under any circumstances. Caution should be used when using chlorhexidine containing preparations, and the patient should be observed for possibility of hypersensitivity reactions.

IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Precautions

SurgiClear™ is not intended to treat catheter-related blood stream infections (CRBSI) or other percutaneous device-related infections and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Hemostasis of any insertion site should be achieved before applying the dressing.

The dressing should not be stretched during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Active Ingredients

Chlorhexidine and Silver reduce the incidence of bacterial colonization under the entire dressing.

Directions for use

Prepare the site as protocol dictates. Open the sterile SurgiClear™ pouch and remove the dressing.

Application:

1. Remove the centre window of the paper backing.
2. Hold the flap of the top blue liner and peel off. Place the exposed adhesive on the skin and smooth the dressing over the skin.
3. Hold the flap of the remaining blue liner and peel off and smooth the dressing over the skin towards the edges.
4. To remove frame; start from the pre-cut line, peel off in a circular motion and smooth the dressing towards the edges to ensure good adhesion.

Site Care:

1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.
2. Inspect the dressing daily and change the dressing as necessary, in accordance with facility protocol. Dressing changes should occur at least every 7 days and may be needed more frequently with highly exudative sites if integrity of the dressing is compromised.
3. The dressing should be changed as necessary:
   - If the dressing becomes loose, soiled or compromised in any way
   - If the site is obscured or no longer visible
   - If there is visible drainage

   Note: SurgiClear™ is not designed to absorb blood or fluid.

Dressing Removal

Change dressing as good nursing practices dictate. To remove the dressing, gently lift one edge of the dressing and slowly peel away.

Storage Information and Shelf Life

- The dressing should be stored in a cool, dry place (≤25°C/75°F).
- Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier until the expiration date printed on the package.
- The expiration date of SurgiClear™ is provided on the package.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured in the USA for: Covalon Technologies Inc., Mississauga (Ontario) L4Z 3E6 Canada
www.covalon.com

™ trademark of Covalon Technologies.

covalon

SurgiClear[MC]

Pansement adhésif antimicrobien en silicone transparent à la chlorhexidine et à l'argent

MODE D'EMPLOI

Description

SurgiClear[MC] est un pansement adhésif antimicrobien en silicone transparent à la chlorhexidine et à l'argent utilisé pour couvrir et protéger les sites de plaie et les dispositifs de fermeture de plaie. SurgiClear[MC] fixe également les pansements primaires à la peau. Le pansement se compose d'un film transparent de polyuréthane enduit d'un adhésif antimicrobien en silicone contenant de la chlorhexidine à 3 % M/M et des sels d'argent à 0,5 % M/M. L'adhésif antimicrobien en silicone de SurgiClear réduit l'incidence d'arrachement de la couche épidermique et est jusqu'à dix fois moins douloureux à l'enlèvement que les pansements contenant des adhésifs acryliques.

SurgiClear[MC] fournit une barrière efficace contre les contaminants externes, y compris les liquides (étanche), les bactéries et les levures. La chlorhexidine et l'argent incorporés dans l'adhésif en silicone assurent une activité antimicrobienne continue tout au long de la période de port recommandée contre un éventail de bactéries Gram-positives et Gram-négatives et contre la levure, dont *Staphylococcus aureus* (SARM), *Staphylococcus epidermidis, Enterococcus faecalis* (ERV), *Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter cloacae, Candida albicans* et *Candida tropicalis*.

SurgiClear[MC] est un film transparent qui permet de surveiller et d'évaluer constamment le site ou la plaie. Le pansement est auto-adhésif et respirable, ce qui permet un bon échange de la vapeur d'eau.

Indications

SurgiClear[MC] est destiné à couvrir et protéger les sites de plaie contre la contamination externe, y compris les plaies postopératoires, débridées ou d'épaisseur partielle, telles que les sites donneurs de greffe de peau, les abrasions, les lacérations, les déchirures cutanées, les brûlures au premier et au deuxième degré.

Le pansement SurgiClear[MC] peut être utilisé pour couvrir et protéger les dispositifs de fermeture de plaie (à savoir les sutures, les agrafes, les clips), les broches orthopédiques, les dispositifs de fixation et les fils ainsi que les drains. SurgiClear[MC] peut également être utilisé pour couvrir et fixer les pansements primaires.

SurgiClear[MC] inhibe la colonisation microbienne et empêche sa revivification sous le pansement.

Avertissements

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ COMME REMPLACEMENT DE SUTURES ET AUTRES MÉTHODES PRIMAIRES DE FERMETURE DE PLAIE.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES BRÛLURES AU TROISIÈME DEGRÉ.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES NOURRISSONS PRÉMATURÉS OU LES NOURRISSONS ÂGÉS DE MOINS DE 2 MOIS. SON UTILISATION SUR DES NOURRISSONS PRÉMATURÉS PEUT ENTRAÎNER DES RÉACTIONS D'HYPERSENSIBILITÉ OU LA NÉCROSE DE LA PEAU.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ COMME MOYEN PRIMAIRE DE FIXER DES CATHÉTERS ARTÉRIELS OU DES CANULES ARTÉRIELLES.

SurgiClear[MC] EST DESTINÉ À UN USAGE EXTERNE UNIQUEMENT ET NE DOIT PAS ÊTRE AUTORISÉ À ENTRER EN CONTACT AVEC LES OREILLES, LES YEUX, LA BOUCHE OU LES MUQUEUSES.

CE PANSEMENT CONTIENT DE L'ARGENT ET PEUVENT PROVOQUER DES IMAGES EN IRM.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES PATIENTS PRÉSENTANT UNE HYPERSENSIBILITÉ OU UNE ALLERGIE CONNUE À L'ARGENT.

SurgiClear[MC] NE DOIT PAS ÊTRE UTILISÉ SUR LES PATIENTS PRÉSENTANT UNE HYPERSENSIBILITÉ OU UNE ALLERGIE CONNUE À LA CHLORHEXIDINE. L'UTILISATION DE PRODUITS CONTENANT DE LA CHLORHEXIDINE A ÉTÉ SIGNALÉE COMME PROVOQUANT DES IRRITATIONS, UNE SENSIBILISATION ET DES RÉACTIONS ALLERGIQUES GÉNÉRALISÉES. Des réactions d'hypersensibilité associées à l'utilisation topique de chlorhexidine ont été signalées dans plusieurs pays. Les réactions les plus graves (y compris l'anaphylaxie) ont été observées chez des patients traités avec des lubrifiants contenant de la chlorhexidine, utilisés lors d'interventions sur le tractus urinaire. Les préparations de ce type ne sont pas approuvées pour la vente aux États-Unis, quelles que soient les circonstances. La prudence est de mise lors de l'utilisation de préparations contenant de la chlorhexidine, et le patient doit être surveillé afin de détecter toute réaction éventuelle d'hypersensibilité.

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SI DES RÉACTIONS ALLERGIQUES SE PRODUISENT, CESSEZ IMMÉDIATEMENT L'UTILISATION. EN PRÉSENCE D'UNE RÉACTION GRAVE, CONTACTEZ UN MÉDECIN.

Précautions

Le pansement SurgiClear[MC] n'est pas destiné à traiter les infections sanguines causées par les cathéters (CRBSI), ni les autres infections causées par les dispositifs percutanés. De plus, le pansement n'a pas fait l'objet d'une étude clinique randomisée quant à son efficacité dans la prévention de telles infections.

L'hémostase de tout site d'insertion doit être réalisée avant d'appliquer le pansement.

Le pansement ne doit pas être étiré lors de l'application. Un traumatisme mécanique de la peau peut se produire si le pansement est apposé en appliquant une tension.

La peau doit être sèche et exempte de résidus de détergent pour prévenir une irritation cutanée et assurer une bonne adhérence. Laissez sécher complètement tous les produits de préparation et de protection avant d'appliquer le pansement pour éviter des irritations de la peau et pour assurer une bonne adhérence.

Ingrédients actifs

La chlorhexidine et l'argent réduisent l'incidence de colonisation bactérienne sous l'ensemble du pansement.

Mode d'emploi

Préparez le site selon les exigences du protocole. Ouvrez le sachet stérile SurgiClear[MC] et retirez le pansement.

Application:

1. Enlever la fenêtre centrale du support papier.
2. Tenez l'aileron du revêtement bleu supérieur et épluchez. Placez l'adhésif exposé sur la peau et lissez le habillage au-dessus de la peau.
3. Tenez le rabat du revêtement bleu restant et retirez-le.
4. Pour enlever le contour; débuter à la ligne prédécoupée; décoller d'un mouvement circulaire et lisser le pansement vers les côtés afin d'assurer une bonne adhérence.

Soins du site:

1. Observez le site chaque jour à la recherche de signes d'infection ou autres complications. Si une infection est soupçonnée, retirez le pansement, inspectez le site directement et déterminez l'intervention médicale appropriée. L'infection peut se manifester par une fièvre, une douleur, une rougeur, une enflure, ou une odeur ou un écoulement inhabituel.
2. Inspectez le pansement chaque jour et changez-le au besoin, conformément au protocole de l'établissement. Les pansements doivent être changés au moins tous les sept (7) jours et peuvent nécessiter d'être changés plus souvent en présence d'une forte quantité d'exsudat si l'intégrité du pansement est compromise.
3. Le pansement doit être changé au besoin:
   - s'il est lâche, sali ou compromis de quelque manière que ce soit;
   - si le site est obscurci ou n'est plus visible,
   - en présence d'un drainage visible.

   Remarque: SurgiClear[MC] n'est pas conçu pour absorber le sang ou les liquides.

Enlèvement du pansement

Changez le pansement conformément aux bonnes pratiques des soins infirmiers. Pour enlever le pansement, soulevez délicatement un bord du pansement puis décollez-le lentement.

Informations d'entreposage et durée de conservation

- Le pansement doit être entreposé dans un endroit frais et sec (à une température inférieure ou égale à 25°C/75°F).
- À condition que l'intégrité de l'emballage ne soit compromise d'aucune façon, l'emballage formera une barrière efficace jusqu'à la date de péremption imprimée sur l'emballage.
- La date de péremption du pansement antimicrobien SurgiClear[MC] est indiquée sur l'emballage.

ATTENTION : La loi fédérale (des États-Unis) n'autorise la vente de ce dispositif que par un médecin ou sur son ordonnance.

Fabriqué aux États-Unis pour: Covalon Technologies Inc., Mississauga (Ontario) L4Z 3E8 Canada www.covalon.com

[MC] Marque de commerce déposée de Covalon Technologies

Product availability / Disponibilité du produit

Product Description / Description du produit	Code	Size / Taille	Box / Boîte
SurgiClear™ (with crosshair) (avec fils croisés)	TWBD1021	4cm x 4cm (1½in x 1½in) / (1½po x 1½po)	25 pouches per carton / sachets par carton
SurgiClear™	TWBD1022	4cm x 4cm (1½in x 1½in) / (1½po x 1½po)	
SurgiClear™	TWBD1017	4cm x 7cm (1½in x 2¾in) / (1½po x 2¾po)	
SurgiClear™	TWBD1018	4cm x 13cm (1½in x 5⅛in) / (1½po x 5⅛po)	
SurgiClear™	TWBD1019	10cm x 12cm (4in x 4¾in) / (4po x 4¾po)	
SurgiClear™	TWBD1023	6cm x 20cm (2⅜in x 8in) / (2⅜po x 8po)	
SurgiClear™	TWBD1024	6cm x 25cm (2⅜in x 10in) / (2⅜po x 10po)	
SurgiClear™	TWBD1025	6cm x 30cm (2⅜in x 12in) / (2⅜po x 12po)	

Not made with natural rubber latex. Sterile unless opened or damaged.
Non fait de latex de caoutchouc naturel. Stérile à moins d'être ouvert ou endommagé.

This is a single use device and should not be re-sterilized.

Ceci est un dispositif à usage unique et il ne doit pas être restérilisé.

STERILE EO

LS-044-2
(ROW)

Questions? Contact FDA/CDRH/OCE/DID at CDRHEOISTATUS@fda.hhs.gov or call 301-796-8118.

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Attachment 8.1
Revised Section 20: Performance Testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PDSTATUS@fda.hhs.gov or call 301-796-8118.

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Section 20- Performance Testing- Clinical

In order to demonstrate substantial equivalence to the predicate SurgiClear™ Antimicrobial Dressing, (b) (4) study was conducted (b) (4) The objective of the study was to assess the adhesive performance (b) (4)
(b)(4) Confidential and Proprietary Information

The adhesive performance of the ReliaTect dressing was assessed in comparison to a commercial reference which represents a comparable standard of care, the SurgiClear™ Antimicrobial Clear Silicone Surgical Dressing. (b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

The study was conducted in accordance with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46). The study was conducted according to the institutional guidelines (b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information

This study was conducted under the supervision of (b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information

The (b) (4) study demonstrated that the ReliaTect Post-Op Dressing with CHG had comparable results to the SurgiClear™ Antimicrobial Clear Silicone Surgical Dressing.
(b)(4) Confidential and Proprietary Information

(b) (4) t can therefore be concluded that the ReliaTect and SurgiClear™ dressings are substantially equivalent in adhesive performance.

Questions? Contact FDA/CDRH at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information - Study Report

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PDSTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Study Report

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