October 10, 2025

Solventum US, LLC
Jamie Thomas
Principal Regulatory Affairs Specialist
12930 IH 10 West
San Antonio, Texas 78249

Re: K251866
Trade/Device Name: Tegaderm™ Post-Op Transparent Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 11, 2025
Received: September 11, 2025

Dear Jamie Thomas:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part

803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MUSTAFA A. MAZHER -S
2025.10.10 13:09:47 -04'00'

For Yu-Chieh Chiu
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251866

Device Name
Tegaderm™ Post-Op Transparent Antimicrobial Dressing

Indications for Use *(Describe)*
The Tegaderm™ Post-Op Transparent Antimicrobial Dressing is a waterproof, single use, sterile dressing with Chlorhexidine Gluconate (CHG), intended to be used on adult patients by healthcare professionals to cover and protect closed surgical incisions or laparoscopic incision and a percutaneous device(s) (e.g., sutures, staples, tissue adhesives).

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:

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"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."

Title: 510(k) Summary K251866

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, provided is the 510(k) summary for Tegaderm Post-Op Transparent Antimicrobial Dressing.

SUMBITTER INFORMATION:

Submitted By: Solventum US LLC
12930 IH 10 West
San Antonio, TX 78249

Contact: Jamie Thomas
Principal Regulatory Affairs Specialist
Phone: (651) 732-0262
Email: jthomas4@solventum.com

DEVICE NAME AND CLASSIFICATION:

Trade Name:	Tegaderm™ Post-Op Transparent Antimicrobial Dressing
Common/Unusual Name:	Dressing, Wound, Drug
Classification:	Unclassified
Product Code:	FRO

PREDICATE DEVICE:

Device Name:	ReliaTect™ Post-Op Dressing
510(k) Number:	K163529

REFERENCE DEVICE:

Device Name:	3M™ Tegaderm™ CHG Chlorhexidine Gluconate Gel Pad
510(k) Number:	K200835

DEVICE DESCRIPTION:

Tegaderm™ Post-Op Transparent Antimicrobial Dressing includes a transparent adhesive dressing and an integrated transparent gel pad containing Chlorhexidine Gluconate (CHG) at a concentration of 1.2% (w/w). The transparent adhesive dressing provides a barrier against

external contamination including fluids (waterproof), bacteria, mold and yeast, and is classified as a breached skin contact device intended for use on closed incisions.

In vitro testing (log reduction and barrier testing) demonstrates that the CHG gel pad in the Tegaderm™ Post-Op Transparent Antimicrobial Dressing has an antimicrobial effect against, gram-positive and gram-negative bacteria, yeast, and mold in the dressing. The gel pad absorbs fluid. Tegaderm™ Post-Op Transparent Antimicrobial Dressing is transparent, allowing for continual site observation, and is breathable, allowing moisture vapor exchange.

The device is sterile. Terminal sterilization is conducted with ethylene oxide.

As part of the Predetermined Change Control Plan, the Tegaderm™ Post-Op Transparent Antimicrobial Dressing design will be updated to include bodily fluid barrier protection. This product requirement will be tested per the *ASTM Method F1670 Synthetic Blood Penetration* standard.

INDICATIONS FOR USE:

The Tegaderm™ Post-Op Transparent Antimicrobial Dressing is a waterproof, single use, sterile dressing with Chlorhexidine Gluconate (CHG), intended to be used on adult patients by healthcare professionals to cover and protect closed surgical incisions or laparoscopic incision and a percutaneous device(s) (e.g., sutures, staples, tissue adhesives).

TECHNOLOGICAL CHARACTERISTICS SUMMARY:

Tegaderm™ Post-Op Transparent Antimicrobial Dressing contains a gel pad with chlorhexidine gluconate to provide antimicrobial effectives against a variety of gram-positive and gram-negative bacteria, yeast, and mold in the dressing. The dressing covers and physically protects the post-operation site while also absorbing exudate, permitting moisture vapor transmission through the film backing (breathable), providing adhesion as a contributing factor of the physical barrier, is transparent, waterproof and is terminally sterilized.

As part of the Predetermined Change Control Plan, the Tegaderm™ Post-Op Transparent Antimicrobial Dressing design will be updated to include bodily fluid barrier protection. This product requirement will be tested per the *ASTM Method F1670 Synthetic Blood Penetration* standard.

SUBSTANTIAL EQUIVALENCE SUMMARY:

The subject device, Tegaderm™ Post-Op Transparent Antimicrobial Dressing demonstrated the same or similar performance to the key features of the predicate device and therefore does not raise any new questions of safety or effectiveness. The provided evidence supports the conclusion that the Tegaderm Post-Op Transparent Antimicrobial Dressing is just as safe and as effective as the legally marketed predicate device.

Table: Subject and Predicate Device Substantial Equivalence Comparison

Features	Subject Device: Tegaderm™ Post-Op Transparent Antimicrobial Dressing	Predicate Device ReliaTect™ Post-Op Dressing (K163529)	Comparison
Indications for use	The Tegaderm Post-Op Transparent Antimicrobial is a waterproof, single use, sterile dressing with Chlorhexidine Gluconate (CHG), intended to be used on adult patients by healthcare professionals to cover and protect closed surgical incisions or laparoscopic incision and a percutaneous device(s) (e.g., sutures, staples, tissue adhesives).	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.	Similar Both products are intended to be single use and intended to be worn up to 7 days even though the ReliaTect™ indications does not call out these intended uses.
Prescription Use	Yes	Yes	Same
Antimicrobial Ingredient	Chlorhexidine Gluconate	Chlorhexidine Gluconate	Same
Antimicrobial Effectiveness	At least an average of 4-log reduction of all eight organisms which includes mold, yeast and bacteria (gram negative and gram positive): *Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecium, Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, Candida albicans* and *Wallemia mellicola,*	A 4 log reduction of gram-positive bacteria, gram negative bacteria, and yeast within the dressing including: *Staphylococcus aureus, Staphylococcus aureus* (MRSA)*, Staphylococcus epidermidis, Enterococcus faecalis* (VRE)*, Escherichia coli, Pseudomonas aeruginosa, Enterobacter aerogenes, Klebsiella pneumonia,* and *Candid albicans*	Similar Both devices tested multiple organisms, but the Tegaderm Post-Op Transparent Antimicrobial Dressing also includes mold testing in support of an antimicrobial intended use.
Fluid Handling Capacity	Yes	Yes	Same
Absorption	Yes	Yes	Same

Features	Subject Device: Tegaderm™ Post-Op Transparent Antimicrobial Dressing	Predicate Device ReliaTect™ Post-Op Dressing (K163529)	Comparison
Adhesion	Yes	Yes	Same
Liner Release	Yes	Yes	Same
Antimicrobial Effectiveness	Yes	Yes	Same
Transparency	Yes	Yes	Same
Waterproof	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Fluid Barrier (per pre-determined change control plan)	Yes	Unknown	Similar. The predicate device declares that it provides barrier functionality, but it is unknown if it specifically provides fluid barrier protection for bodily fluids
Dimensions	9.2 cm x 10 cm 9.2 cm x 15 cm 9.2 cm x 20 cm 9.2 cm x 25 cm 9.2 cm x 30 cm 9.2 cm x 34 cm	5 cm x 15 cm 10 cm x 25 cm	Similar. Performance testing is provided to support that while there is a wider range of dressings sizes for the subject device, the different technological characteristics of the products do not raise different questions of safety and effectiveness.

PERFORMANCE DATA SUMMARY

Nonclinical Testing:

The Tegaderm™ Post-Op Transparent dressing was designed and bench tested against the categories noted below. When available, the applicable standards and guidance documents were used for design and testing in support of substantial equivalence.

Absorption
Moisture Vapor Transmission Rate
Adhesion
Liner Release
Antimicrobial Effectiveness
Transparency

CONCLUSION:
The subject device, Tegaderm™ Post-Op Transparent Antimicrobial Dressing demonstrated the same or similar performance to the key features of the predicate device and therefore does not raise any new questions of safety or effectiveness. The provided evidence supports the conclusion that the Tegaderm™ Post-Op Transparent Antimicrobial Dressing is just as safe and as effective as the legally marketed predicate device.