May 21, 2026

MoleculeX Co., Ltd.
% Anita Chen
Advisor of Regulatory Affair
ZhengCheng Consulting Limited Company
#19, Fuxing Rd., 335 Lane, Shuling Dist.,
New Taipei, 238
Taiwan

Re: K253816
Trade/Device Name: MuCover (proposed name) Oral Wound Dressing
Regulatory Class: Unclassified
Product Code: OLR, MGQ
Dated: November 28, 2025
Received: November 28, 2025

Dear Anita Chen:

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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253816

Please provide the device trade name(s).

MuCover (proposed name) Oral Wound Dressing

Please provide your Indications for Use below.

Oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary K253816

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

The assigned 510(k) Number: Pending

1.	Submitter:	
	Sponsor	MoleculeX Co., Ltd.
	Mailing Address	2F, No. 18, Lane 127, Minzu Rd., E. Dist., Hsinchu City, Taiwan
	Contact Person	Anita Chen
	Cell Phone:	+886-939-855-759
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	E-mail:	m9104303@gmail.com
	Date Prepared	Oct/31/2025

2.	Subject Device:	
	Proprietary Name:	Oral Wound Dressing
	Trade Name:	MuCover (Proposed name)
	Regulation Number:	
	Regulation Name:	Oral Wound Dressing
	Regulatory Class:	Unclassified
	Product Code:	OLR, MGQ

3.	Predicate Device:	
	510(k) number	K211851
	Device Name:	Intra-oral Wound Dressing
	Trade Name:	Ora-Aid
	Regulation Name:	Oral Wound Dressing
	Regulatory Class:	Unclassified
	Product Code:	OLR, MGQ

4.	Device Description:	Oral Wound Dressing is a device comprised of an oral mucosa adhesive side and a protection side. The oral mucosa adhesive side is composed of a water-soluble polymer that when exposed to moisture in the oral cavity changes into a gel state to achieve adhesion to the wound area. The protection side consists of a water insoluble polymer which covers the wound to protect the applicable area from the environment in the oral cavity. Oral Wound Dressing is simply a non-sterile bandage to protect oral wounds.
5.	Intended Use:	Oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.
6.	Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that MoleculeX Co., Ltd. Oral Wound Dressing, is substantially equivalent to the predicate device as summarized in Table 1. The differences raise no new question of safety and effectiveness.

Table 1

Items	Subjective device	Predicate device	Comments
Product name	Oral Wound Dressing	Intra-oral Wound Dressing	different
Device name	MuCover (Proposed name)	Ora-Aid	different
Manufacturer	MoleculeX Co., Ltd.	TBM Corporation	different
510k Number	TBD	K211851	
Classification	Oral Wound Dressing	Oral Wound Dressing	same

Intended Use/ indication for use	Oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.	Intra-oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Intra-oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.	similar
Product Code	OLR, MGQ	MGQ, OLR	similar
Anatomical sites	Oral mucosa surface	Oral mucosa surface	same
Where Used	In hospitals/clinics/home use; applied topically to mucosal surfaces	In hospitals/clinics, applied topically to mucosal surfaces	similar
Design	Two-layer mucoadhesive patch for oral application.	Two-layer mucoadhesive patch for oral application.	same
Method of Introduction	It reverts to a soft and gel-type thin sheet in the oral environment and adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.	It reverts to a soft and gel-type thin sheet in the oral environment and adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.	same
Mechanics of Action	Polymer	Polymer	same

OTC/Prescription Use	Prescription Use / OTC (Suitable for OTC use: single-use, non-medicated device providing only physical protection; poses no pharmacological, metabolic, or immunological risk.)	Prescription Use	similar
Single/Multiple Use	Single	Single	same
Biocompatibility	1. Cytotoxicity Test ISO 10993-5:2009 2. Skin Sensitization Study in Guinea Pigs ISO 10993-10:2021 3. Acute Systemic Toxicity Study ISO 10993-11:2017 4. Pyrogen Study in Rabbits USP 47/NF42:2024 <151> and ISO/TR 21582:2021	1. Cytotoxicity ISO 10993-5:2009 2. Sensitization ISO 10993-10:2010 3. Intracutaneous Reactivity Test ISO 10993-10:2010 4. Acute Systemic Toxicity Test ISO 10993-11:2016 5. Material-Mediated Pyrogen Test ISO 10993-11:2016	similar
Contact the body directly or indirectly	Contact the body directly	Contact the body directly	same
Contact duration	11hours *Based on in-vitro static mucosal model testing; however, actual performance may be influenced by the complex physiological and mechanical conditions of the oral environment.	4 hours (Adhesion time)	Different (No additional risks were observed, and all results remained within the 24-hour evaluation range.)
Sterility	None	None	Same
Technological characteristics			

Size	Square [S3535] 35mm x 35mm x (0.4-0.5)mm [WxLxT] [S5100] 50mm x 100mm x (0.4-0.5)mm [WxLxT] [S5015] 50mm x 15mm x (0.4-0.5)mm [WxLxT] [S2515] 25mm x 15mm x (0.4-0.5)mm [WxLxT] Circular [C0015] 15mm x (0.4-0.5)mm [DxT] [C0012] 12mm x (0.4-0.5)mm [DxT]	AD12: 12mm x (0.3~0.399)mm [DxT] OB23: 25mm x 15mm x (0.3~0.399)mm [WxLxT] OB53: 50mm x 15mm x (0.3~0.399)mm [WxLxT]	Different (The difference in size or configuration does not affect the product's safety or effectiveness.)

7. Performance and Safety Test:
   a. Performance Testing:

Based on the information provided herein, MoleculeX Co., Ltd. concludes that the Oral Wound Dressing is substantially equivalent to the predicate devices for the intended use, physical and procedural characteristics, performance, safety characteristics, and labeling. The Oral Wound Dressing subject device incorporates same design features, procedural steps, and performance characteristics when compared to the predicate devices.

Non-clinical testing, including bench test of the Oral Wound Dressing, has shown that the subject device meets the functional, performance, and safety requirements for the indications shared by the subject and predicate devices intended use to maintain the oral wound site. The Performance testing further confirms that the use of the Oral Wound Dressing can effectively maintain the dressing on wound site. The performance requirements for the subject Oral Wound Dressing successfully met the intended use.

From the comparison performance testing with predicate device confirmed that the Oral Wound Dressing performs as intended and does not raise any new issues of safety and effectiveness, as compared with the predicate device, for use to maintain oral wound.

b. Biocompatibility Testing:
The biocompatibility evaluation and testing was conducted in accordance with the following standards and guidance, as recognized by the FDA:
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
- ISO 10993-11, Biological evaluation of medical devices - Part 23: Tests for acute systemic toxicity test.

8. Conclusion:
Based on the intended use and/or indications for use, technological characteristics, performance testing, and comparison with the predicate device, the MoleculeX Co., Ltd. Oral Wound Dressing is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness.