

K253816 MuCover (proposed name) Oral Wound DressingMay 21, 2026
174 days to decisionK253816 · Product code: **OLR** · Dental
Source: <https://www.510kdatabase.net/k253816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Nov 28, 2025
Decision date	May 21, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MoleculeX Co., Ltd.
Location	Hsinchu, TW
Contact	ShihYung Liao
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	ZhengCheng Consulting Limited Company
Contact	Anita Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026