

K250512 Augmented Gingival MatrixDec 5, 2025
287 days to decisionK250512 · Product code: **NPL** · DentalSource: <https://www.510kdatabase.net/k250512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Feb 21, 2025
Decision date	Dec 5, 2025
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neo Modulus (Suzhou) Medical Sci-Tech Co., Ltd.
Location	Suzhou, CN
Contact	Jade Guo
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250512/> 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 May 14, 2026