

K222025 G4Derm / G4Derm Plus Synthetic Wound MatrixOct 11, 2023
457 days to decisionK222025 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jul 11, 2022
Decision date	Oct 11, 2023
Days to decision	457 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gel4med, Inc.
Location	Brighton, MA, US
Contact	Ana Tellechea
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222025/> 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 26, 2026