

K251582 Redermax Antibacterial Wound MatrixFeb 2, 2026
255 days to decisionK251582 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 23, 2025
Decision date	Feb 2, 2026
Days to decision	255 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Kreate Medical Co., Ltd.
Location	Beijing, CN
Contact	Sean Chen
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Scientific Horizons Consulting, LLC
Contact	Christopher Swanson

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/k251582/> 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