

**K243181 Foundation Dermal Regeneration Scaffold Plus (DRS+)
Solo**Oct 31, 2024
31 days to decisionK243181 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 30, 2024
Decision date	Oct 31, 2024
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bionova Medical, Inc.
Location	Alexandria, VA, US
Contact	Alex Greene
510(k) history	6 submissions · 6 cleared · 2012-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Lucie Dalet

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/k243181/>; 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