

K231937 Foundation Dermal Regeneration Scaffold (DRS) SoloNov 13, 2023
136 days to decisionK231937 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jun 30, 2023
Decision date	Nov 13, 2023
Days to decision	136 days
Third-party review	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

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