

K210949 Foundation Dermal Regeneration Scaffold (DRS) SoloAug 11, 2022
499 days to decisionK210949 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Mar 30, 2021
Decision date	Aug 11, 2022
Days to decision	499 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

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