

K241904 DermiSphere Dermal TemplateJan 6, 2025
189 days to decisionK241904 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k241904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jul 1, 2024
Decision date	Jan 6, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fesariustherapeutics, Inc.
Location	Brooklyn, NY, US
Contact	Yulia Sapir-Lekhovitser
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Regenity Biosciences
Contact	Diana Bordon

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/k241904/> 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 13, 2026