

K250864 MatriDerm pluS+ Bi-LayerDec 19, 2025
273 days to decisionK250864 · Product code: **KG N** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Mar 21, 2025
Decision date	Dec 19, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medskin Solutions Dr. Suwelack AG
Location	Billerbeck, DE
Contact	Jan Hermes
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Justin Gracyalny

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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