

K251323 Device 104 ParticulateJan 22, 2026
268 days to decisionK251323 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Apr 29, 2025
Decision date	Jan 22, 2026
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Geistlich Pharma AG
Location	Washington, DC, US
Contact	Jan Van der Ploeg
510(k) history	26 submissions · 26 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Veronica Downen

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251323/> 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