

K232758 Comatrix OTCDec 1, 2023
84 days to decisionK232758 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Sep 8, 2023
Decision date	Dec 1, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Strukmyer Medical, LLC
Location	Mesquite, TX, US
Contact	Christian Quinto
510(k) history	2 submissions · 2 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Richard Hamer Associates, LLC
Contact	Richard Hamer

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/k232758/> 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 26, 2026