

K223257 Miro3D Wound MatrixNov 21, 2022
31 days to decisionK223257 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Oct 21, 2022
Decision date	Nov 21, 2022
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reprise Biomedical
Location	Plymouth, MN, US
Contact	Carrie Powers
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Kathy Herzog

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/k223257/> 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 25, 2026