

**K212579 FortiShield (Biosynthetic Wound Matrix)**May 2, 2023  
624 days to decisionK212579 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212579/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Aug 16, 2021
Decision date	May 2, 2023
Days to decision	624 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Organogenesis, Inc.</b>
Location	Canton, MA, US
Contact	Christina Nichols
510(k) history	12 submissions · 12 cleared · 1997-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212579/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026