

**K250329 GeniPhys Collymer Self-Assembling Scaffold**Jun 25, 2025  
140 days to decisionK250329 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250329/>**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	Feb 5, 2025
Decision date	Jun 25, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Geniphys, Inc.</b>
Location	Indianapolis, IN, US
Contact	Sherry Harbin
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250329/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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