

**K254034 Roosin Collagen Powder**Jun 3, 2026  
169 days to decisionK254034 · Product code: **KGN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k254034/>**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	Dec 16, 2025
Decision date	Jun 3, 2026
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roosin Medical Co., Ltd.</b>
Location	Taizhou, CN
Contact	Dayong Chen
510(k) history	5 submissions · 5 cleared · 2019-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manton Business and Technology Services</b>
Contact	Charles Shen

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

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