

K253974 Roosin Collagen DressingJun 3, 2026
174 days to decisionK253974 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Dec 11, 2025
Decision date	Jun 3, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
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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