

**K252001 Collagen Wound Dressing**Oct 10, 2025  
105 days to decisionK252001 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252001/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jun 27, 2025
Decision date	Oct 10, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Winner Medical Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Ziling Shangguan
510(k) history	18 submissions · 18 cleared · 2019-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252001/> 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