

**K213598 LUOFUCON Collagen Wound Dressing**Sep 20, 2022  
309 days to decisionK213598 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213598/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Nov 15, 2021
Decision date	Sep 20, 2022
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Huizhou Foryou Medical Devices Co., Ltd.</b>
Location	Pennington, NJ, US
Contact	Taylor Deng
510(k) history	22 submissions · 22 cleared · 2012-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213598/> 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 14, 2026