

K252028 LUOFUCON® Antimicrobial Wound GelMar 11, 2026
254 days to decisionK252028 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 30, 2025
Decision date	Mar 11, 2026
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huizhou Foryou Medical Co., Ltd.
Location	Huizhou, CN
Contact	Huiqi Huang
Website	https://www.foryoumedical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Huizhou Foryou Medical Co., Ltd. is a medical device manufacturer based in Huizhou, China. The company develops and markets wound care and surgical products for clinical use. The company has received FDA 510(k) clearance from total submission. Its regulatory focus centers on General & Plastic Surgery devices. The company achieved its first FDA clearance in 2026 and remains active in regulatory submissions. Notable cleared products include LUOFUCON® Antimicrobial Wound Gel, a specialized wound care solution. This product reflects the company's expertise in antimicrobial an...