

K201324 Antibacterial BandageFeb 5, 2021
263 days to decisionK201324 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 18, 2020
Decision date	Feb 5, 2021
Days to decision	263 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Excellence Medical Supplies Co., Ltd.
Location	Changzhou, CN
Contact	Yanhua Li
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201324/>; Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026