

K221311 Antibacterial BandageJun 21, 2023
412 days to decisionK221311 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 5, 2022
Decision date	Jun 21, 2023
Days to decision	412 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Winner Medical Co., Ltd.
Location	Shenzhen, CN
Contact	Yi Fu
510(k) history	18 submissions · 18 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221311/> 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 13, 2026