

K221532 PHMB Wound DressingJan 30, 2023
249 days to decisionK221532 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 26, 2022
Decision date	Jan 30, 2023
Days to decision	249 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/k221532/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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