

K181315 Antimicrobial gauze sponge dressing, Antimicrobial super sponge dressing, Antimicrobial non-woven sponge dressingFeb 14, 2019
272 days to decisionK181315 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 18, 2018
Decision date	Feb 14, 2019
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181315/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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