

K181478 Roosin Xeroform Petrolatum DressingSep 13, 2019
465 days to decisionK181478 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 5, 2018
Decision date	Sep 13, 2019
Days to decision	465 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roosin Medical Co., Ltd.
Location	Taizhou, CN
Contact	Charles Shen
510(k) history	3 submissions · 3 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181478/> 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 26, 2026