

**K231088 Copper Foam Dressing (Prescription and OTC)**Jan 11, 2024  
269 days to decisionK231088 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 17, 2023
Decision date	Jan 11, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roosin Medical Co., Ltd.</b>
Location	Taizhou, CN
Contact	Dayong Chen
510(k) history	3 submissions · 3 cleared · 2019-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manton Business and Technology Services</b>
Contact	Charles Shen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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