

**K192463 PHMB Foam Dressing Non-Adhesive, PHMB Foam Dressing Adhesive, Silicone PHMB Foam Dressing, Silicone PHMB Foam Dressing with Border**May 14, 2020  
248 days to decisionK192463 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k192463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 9, 2019
Decision date	May 14, 2020
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192463/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026