

**K201016 LUOFUCON PHMB Alginate Dressing (Rx use),  
LUOFUCON PHMB Antibacterial Alginate Wound Dressing (OTC  
use)**Jan 28, 2021  
286 days to decisionK201016 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 17, 2020
Decision date	Jan 28, 2021
Days to decision	286 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huizhou Foryou Medical Devices Co., Ltd.</b>
Location	Pennington, NJ, US
Contact	Guosheng Tan
510(k) history	22 submissions · 22 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201016/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026