

**K252167 Enhanced Silver Gelling Fiber Dressing (OTC) Extra  
Enhanced Silver Gelling Fiber Dressing (Prescription)**Dec 19, 2025  
162 days to decisionK252167 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252167/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jul 10, 2025
Decision date	Dec 19, 2025
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Qingdao Bright Moon Biomedical Materials Co., Ltd.</b>
Location	Qingdao, CN
Contact	Yunlong Deng
510(k) history	2 submissions · 2 cleared · 2023-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252167/> 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 14, 2026