

**K242089 Vitrification Freeze Kit (RFD-0101) Vitrification Thaw Kit (RFD-0201, RFD-0202)**Apr 10, 2025  
267 days to decisionK242089 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k242089/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 17, 2024
Decision date	Apr 10, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Ruifuda Medical Device Co., Ltd.</b>
Location	Lianyungang, CN
Contact	Jingkai Shao
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Osmunda Medical Device Technical Service Co., Ltd.</b>
Contact	Olivia Meng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242089/> 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 14, 2026