FDA 510(k) Premarket Notification

K242089 Vitrification Freeze Kit (RFD-0101) Vitrification Thaw Kit (RFD-0201, RFD-0202)

CLEARED

Apr 10, 2025
267 days to decision

K242089 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k242089/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Osmunda Medical Device Technical Service Co., Ltd.**
Contact	Olivia Meng

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