

K241341 cryo-GO Vitrification DeviceSep 26, 2024
136 days to decisionK241341 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	May 13, 2024
Decision date	Sep 26, 2024
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Irvine Scientific
Location	Santa Ana, CA, US
Contact	Cindy Kha
510(k) history	4 submissions · 4 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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