FDA 510(k) Premarket Notification

K241341 cryo-GO Vitrification Device

CLEARED

Sep 26, 2024
136 days to decision

K241341 · Product code: **MQK** · Obstetrics & Gynecology
Source: 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