

K250445 Fast Warm - NXSep 12, 2025
210 days to decisionK250445 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Feb 14, 2025
Decision date	Sep 12, 2025
Days to decision	210 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/k250445/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026