FDA 510(k) Premarket Notification

K251305 Ultra-Fast Vitri

CLEARED

Aug 26, 2025
120 days to decision

K251305 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k251305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Apr 28, 2025
Decision date	Aug 26, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ultra-Fast Warm

APPLICANT

Company	**Kitazato Corporation**
Location	Tokyo, JP
Contact	Kyoko Izumi
510(k) history	13 submissions · 13 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Mei Li

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