

**K251305 Ultra-Fast Vitri**Aug 26, 2025  
120 days to decisionK251305 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k251305/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Mei Li

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

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251305/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026