

K260248 Ultra-Fast WarmApr 28, 2026
91 days to decisionK260248 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k260248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jan 27, 2026
Decision date	Apr 28, 2026
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	BIOMEDICAL SUPPLY S.L. DBA DIBIMED
Contact	Belén Fos Guarinos

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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