

K202862 Gx-IVF, Gx-TL, Gx-MOPS PLUSMay 14, 2021
228 days to decisionK202862 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202862/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Sep 28, 2020
Decision date	May 14, 2021
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vitrolife Sweden AB
Location	Ringoes, NJ, US
Contact	Sarah Hood Hagberg
510(k) history	38 submissions · 38 cleared · 2000-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202862/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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