

K242640 FertiCult Flushing mediumMay 30, 2025
269 days to decisionK242640 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k242640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Sep 3, 2024
Decision date	May 30, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FertiCult Flushing medium with phenol red and gentamicin

APPLICANT

Company	Fertipro NV
Location	Irvine, CA, US
Contact	Liesbeth Faes
Website	https://fertipro.com/
510(k) history	4 submissions · 4 cleared · 2006-2025

Fertipro NV is an independent manufacturer of in vitro diagnostics and cell culture media for assisted reproductive technologies and male infertility diagnosis. Founded in 1992, the company operates a state-of-the-art manufacturing facility in Beernem, Belgium, with FDA registration in Irvine, US. Fertipro holds ISO 13485 certification and participates in the MDSAP program. The company has received FDA 510(k) clearances from total submissions since 2006. Obstetrics & Gynecology devices dominate the regulatory portfolio, representing 75% of submissions. The latest clearanc...

REGULATORY CONSULTANT

Consulting firm	Rock Quality Systems
Contact	Sarah Robbins

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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Device record: <https://www.510kdatabase.net/k242640/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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