

K053494 OIL FOR TISSUE CULTURE, GRADIENT SYSTEM AND SPERMFREEZEMar 23, 2006
98 days to decisionK053494 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k053494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Dec 15, 2005
Decision date	Mar 23, 2006
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fertipro NV
Location	Irvine, CA, US
Contact	GRACE HOLLAND
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...

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