

**K070135 VITRIFREEZE MEDIUM**Aug 16, 2007  
212 days to decisionK070135 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k070135/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jan 16, 2007
Decision date	Aug 16, 2007
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary
Other names	VITRITHAW MEDIUM

**APPLICANT**

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Company	<b>Fertipro NV</b>
Location	Irvine, CA, US
Contact	GRACE HOLLAND
Website	<a href="https://fertipro.com/">https://fertipro.com/</a>
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...