

**K090832 RAPID-I**Dec 23, 2009  
272 days to decisionK090832 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k090832/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Mar 26, 2009
Decision date	Dec 23, 2009
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitrolife Sweden AB</b>
Location	Ringoes, NJ, US
Contact	KJELL KJORK
510(k) history	38 submissions · 38 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090832/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 21, 2026