

K081114 G-1 V5Sep 16, 2008
151 days to decisionK081114 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k081114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Apr 18, 2008
Decision date	Sep 16, 2008
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081114/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026