

**K150950 FreezeKit Cleave , ThawKit Cleave**Dec 21, 2015  
257 days to decisionK150950 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k150950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Apr 8, 2015
Decision date	Dec 21, 2015
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitrolife Sweden AB</b>
Location	Ringoes, NJ, US
Contact	Brett Sonet Glazar
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/k150950/> 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 3, 2026