

**K193285 V-ONESTEP**Nov 20, 2020  
359 days to decisionK193285 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k193285/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 27, 2019
Decision date	Nov 20, 2020
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitromed GmbH</b>
Location	Jena, DE
Contact	Deepesh Changat
510(k) history	7 submissions · 7 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193285/> 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 May 26, 2026