

K223117 V-SPERM WASHJan 31, 2023
120 days to decisionK223117 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k223117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 3, 2022
Decision date	Jan 31, 2023
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vitromed GmbH
Location	Jena, DE
Contact	Greg Holland
510(k) history	7 submissions · 7 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Specialists, Inc.
Contact	Greg Holland

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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