

K213293 V-HEPES PLUSSep 14, 2022
348 days to decisionK213293 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k213293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 1, 2021
Decision date	Sep 14, 2022
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vitromed Langenfeld
Location	Langenfeld, DE
Contact	Greg Holland
510(k) history	1 submissions · 1 cleared · 2022-2022

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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