FDA 510(k) Premarket Notification

K232125 V-PVP

CLEARED

Mar 20, 2024
247 days to decision

K232125 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k232125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 17, 2023
Decision date	Mar 20, 2024
Days to decision	247 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