FDA 510(k) Premarket Notification

K240176 V-VITFREEZE and V-VITWARM

CLEARED

Sep 13, 2024
234 days to decision

K240176 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k240176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jan 23, 2024
Decision date	Sep 13, 2024
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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