FDA 510(k) Premarket Notification

K202862 Gx-IVF, Gx-TL, Gx-MOPS PLUS

CLEARED

May 14, 2021
228 days to decision

K202862 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k202862/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Sep 28, 2020
Decision date	May 14, 2021
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitrolife Sweden AB**
Location	Ringoes, NJ, US
Contact	Sarah Hood Hagberg
510(k) history	38 submissions · 38 cleared · 2000-2025