FDA 510(k) Premarket Notification

K133568 G-TL

CLEARED

Jul 16, 2014
238 days to decision

K133568 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k133568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 20, 2013
Decision date	Jul 16, 2014
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vitrolife, Inc.**
Location	Englewood, CO, US
Contact	MARK LARMAN
510(k) history	1 submissions · 1 cleared · 2014-2014