FDA 510(k) Premarket Notification

K081114 G-1 V5

CLEARED

Sep 16, 2008
151 days to decision

K081114 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k081114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Apr 18, 2008
Decision date	Sep 16, 2008
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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