FDA 510(k) Premarket Notification

K161970 Follicle Aspiration Set

CLEARED

Jun 14, 2017
331 days to decision

K161970 · Product code: **MQE** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k161970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Jul 18, 2016
Decision date	Jun 14, 2017
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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