

K161970 Follicle Aspiration SetJun 14, 2017
331 days to decisionK161970 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161970/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026