

K181461 Rapid-i™ KitJan 4, 2019
214 days to decisionK181461 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Jun 4, 2018
Decision date	Jan 4, 2019
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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