

K140207 RAPID-I KITDec 18, 2014
324 days to decisionK140207 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k140207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Jan 28, 2014
Decision date	Dec 18, 2014
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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