

K180740 VitriGuardMay 4, 2018
43 days to decisionK180740 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k180740/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Mar 22, 2018
Decision date	May 4, 2018
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Origio A/S
Location	San Diego, CA, US
Contact	Roaida Johnson
510(k) history	14 submissions · 14 cleared · 2010-2020

REGULATORY CONSULTANT

Consulting firm	CooperSurgical, Inc.
Contact	Roaida Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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