

**K200815 VitriGuard**Jun 25, 2020  
87 days to decisionK200815 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200815/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Mar 30, 2020
Decision date	Jun 25, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Origio A/S</b>
Location	San Diego, CA, US
Contact	Christine Kupchick
510(k) history	14 submissions · 14 cleared · 2010-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>CooperSurgical, Inc.</b>
Contact	Christine Kupchick

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200815/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 20, 2026