

K153267 ORIGIO Gradient 100, ORIGIO Gradient 90, ORIGIO Gradient 40/80, ORIGIO Sperm WashJul 22, 2016
253 days to decisionK153267 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k153267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 12, 2015
Decision date	Jul 22, 2016
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153267/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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