

K173624 ORIGIO® Handling™ without phenol red (Cat. No. 8310), ORIGIO® Handling™ with phenol red (Cat. No. 8311)Mar 2, 2018
98 days to decisionK173624 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k173624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 24, 2017
Decision date	Mar 2, 2018
Days to decision	98 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	Tove Kjaer
510(k) history	14 submissions · 14 cleared · 2010-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173624/>. Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026