

**K172197 SAGE 1-Step GM-CSF with HSA, SAGE 1-Step GM-CSF with SPS**Oct 13, 2017  
84 days to decisionK172197 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k172197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 21, 2017
Decision date	Oct 13, 2017
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172197/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026