

**K190383 GM501 Wash**Sep 5, 2019  
198 days to decisionK190383 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k190383/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Feb 19, 2019
Decision date	Sep 5, 2019
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hamilton Thorne, Inc.</b>
Location	Beverly, MA, US
Contact	Donald Fournier
510(k) history	4 submissions · 4 cleared · 2012-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190383/> 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 May 27, 2026