

**K153591 ebb Complete Tamponade System**Jan 14, 2016  
29 days to decisionK153591 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k153591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	Dec 16, 2015
Decision date	Jan 14, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clinical Innovations, LLC</b>
Location	Murray, UT, US
Contact	TOM HAUETER
510(k) history	9 submissions · 9 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153591/> 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 26, 2026