

**K160864 Cryotop Vitrification Kit and Cryotop Thawing Kit**Oct 7, 2016  
192 days to decisionK160864 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Mar 29, 2016
Decision date	Oct 7, 2016
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kitazato Biopharma Co;Ltd</b>
Location	Austin, TX, US
Contact	FUTOSHI INOUE
510(k) history	6 submissions · 6 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160864/> 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 2, 2026