

K112695 CRYOTOPDec 12, 2012
454 days to decisionK112695 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k112695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Sep 15, 2011
Decision date	Dec 12, 2012
Days to decision	454 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kitazato Biopharma Co;Ltd
Location	Austin, TX, US
Contact	RICHARD VINCINS CQA,RAC(US,EU)
510(k) history	6 submissions · 6 cleared · 2012-2016

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