

**K180304 Geri Embryo Incubator and Geri Dish**Apr 20, 2018  
77 days to decisionK180304 · Product code: **MQG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k180304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Feb 2, 2018
Decision date	Apr 20, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genea Biomedx Pty, Ltd.</b>
Location	Sydney, AU
Contact	Kea Dent
510(k) history	6 submissions · 6 cleared · 2017-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180304/> 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 30, 2026