

K180188 Geri Embryo Incubator with Geri Connect and Geri Assess Software, and Geri DishJun 7, 2018
135 days to decisionK180188 · Product code: **MQG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k180188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Jan 23, 2018
Decision date	Jun 7, 2018
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180188/> Data sourced from FDA 510(k) public records (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. - Generated May 30, 2026