

K161261 Gems Geri Medium, Gems Fertilisation Medium, Gems Cleavage Medium, Gems Blastocyst Medium, Gems VitBaseMay 12, 2017
373 days to decisionK161261 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k161261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	May 4, 2016
Decision date	May 12, 2017
Days to decision	373 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/k161261/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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