

K162409 Gems Vitrification Set, Gems Warming SetMay 24, 2017
268 days to decisionK162409 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k162409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Aug 29, 2016
Decision date	May 24, 2017
Days to decision	268 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/k162409/> 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