

**K170498 Gems Oocyte Retrieval Buffer ORB-20, ORB-50**Sep 28, 2017  
223 days to decisionK170498 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k170498/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Media, Reproductive (MQL)          |
| Date received         | Feb 17, 2017                       |
| Decision date         | Sep 28, 2017                       |
| Days to decision      | 223 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/k170498/> 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