

K183486 RapidVit™ Oocyte, RapidWarm™ OocyteJul 26, 2019
221 days to decisionK183486 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k183486/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | Dec 17, 2018 |
| Decision date | Jul 26, 2019 |
| Days to decision | 221 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Vitrolife Sweden AB |
| Location | Ringoes, NJ, US |
| Contact | Nina Arvidsson |
| 510(k) history | 38 submissions · 38 cleared · 2000-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183486/> 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 13, 2026