

**K162051 Cryotec**Dec 14, 2016  
142 days to decisionK162051 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k162051/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Labware, Assisted Reproduction (MQK) |
| Date received         | Jul 25, 2016                         |
| Decision date         | Dec 14, 2016                         |
| Days to decision      | 142 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Reprolife, Inc.</b>                |
| Location       | Shinjuku-Ku, JP                       |
| Contact        | KOICHI TAKEDA                         |
| 510(k) history | 1 submissions · 1 cleared · 2016-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162051/> 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 June 2, 2026