

K190199 SepaSperm Washing Solution, SepaSperm SolutionSep 26, 2019
234 days to decisionK190199 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190199/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | Feb 4, 2019 |
| Decision date | Sep 26, 2019 |
| Days to decision | 234 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Kitazato Corporation |
| Location | Tokyo, JP |
| Contact | Futoshi Inoue |
| 510(k) history | 13 submissions · 13 cleared · 2017-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190199/> 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 26, 2026