

K043116 ICSI-100Jan 13, 2005
64 days to decisionK043116 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k043116/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | Nov 10, 2004 |
| Decision date | Jan 13, 2005 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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