

**K983580 BLASTOCYST MEDIUM**Feb 18, 1999  
128 days to decisionK983580 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k983580/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Media, Reproductive (MQL)          |
| Date received         | Oct 13, 1998                       |
| Decision date         | Feb 18, 1999                       |
| Days to decision      | 128 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Irvine Scientific Sales Co., Inc.</b> |
| Location       | Santa Ana, CA, US                        |
| Contact        | ROBERTA L JOHNSON                        |
| 510(k) history | 40 submissions · 40 cleared · 1997-2017  |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983580/> 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 1, 2026