

K151367 Sydney IVF HyaluronidaseJan 27, 2016
251 days to decisionK151367 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k151367/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | May 21, 2015 |
| Decision date | Jan 27, 2016 |
| Days to decision | 251 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | William A. Cook Australia Pty. , Ltd. |
| Location | Eight Mile Plains, Qld, AU |
| Contact | GORDANA POZVEK |
| 510(k) history | 14 submissions · 14 cleared · 2009-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151367/> 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 30, 2026