

**K011346 READYSWIM**Jun 28, 2001  
57 days to decisionK011346 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k011346/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Media, Reproductive (MQL)          |
| Date received         | May 2, 2001                        |
| Decision date         | Jun 28, 2001                       |
| Days to decision      | 57 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nidacon International AB</b>         |
| Location       | Deer Field, IL, US                      |
| Contact        | DANIEL KAMM                             |
| 510(k) history | 12 submissions · 12 cleared · 1998-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011346/> 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 7, 2026