

**K131145 PROINSERT**Feb 20, 2014  
303 days to decisionK131145 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k131145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Apr 23, 2013
Decision date	Feb 20, 2014
Days to decision	303 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/k131145/> 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