

**K983596 INTRACYTOPLASMIC SPERM INJECTION (ICSI)  
MICRO-INJECTION PIPETTES, HOLDING PIPETTES, DENUDING  
PIPETTES, ASSISTED HATCHING**Feb 5, 1999  
115 days to decisionK983596 · Product code: **MQH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k983596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microtools, Assisted Reproduction (pipettes) (MQH)
Date received	Oct 13, 1998
Decision date	Feb 5, 1999
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ob/Gyn</b>
Location	Bloomington, IN, US
Contact	DEBBIE SCHMITT
510(k) history	43 submissions · 43 cleared · 1985-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983596/> 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 29, 2026