

K033903 MODIFICATION TO INTRACYTOPLASMIC SPERM INJECTION (ISCI), MICRO-INJECTION PIPETTES, HOLDING PIPETTES, DENUDING PIPETTES,Jan 16, 2004
30 days to decisionK033903 · Product code: **MQH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k033903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Microtools, Assisted Reproduction (pipettes) (MQH)
Date received	Dec 17, 2003
Decision date	Jan 16, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	BRENDA DAVIS
510(k) history	104 submissions · 102 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033903/> 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 June 19, 2026