

**K990847 INTRACYTOPLASMIC SPERM INJECTION  
MICROPIPETS (ICSI) SPERMATID ICSI MICROPIPETS,  
HOLDING MICROPIPETS, ASSISTED HATCHING M**Jul 14, 1999  
121 days to decisionK990847 · Product code: **MQH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k990847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microtools, Assisted Reproduction (pipettes) (MQH)
Date received	Mar 15, 1999
Decision date	Jul 14, 1999
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Humagen Fertility Diagnostics, Inc.</b>
Location	Charlottesville, VA, US
Contact	CINDY SHOWALTER
510(k) history	5 submissions · 5 cleared · 1994-2002

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