

K991388 ASSISTED HATCHING MICROPIPETTES, DENUDING PIPETTES, HOLDING MICROPIPETTES, ICSI MICROPIPETTES, PARTIAL ZONE DISSECTION M

Sep 13, 1999
145 days to decision

K991388 · Product code: **MQH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k991388/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microtools, Assisted Reproduction (pipettes) (MQH)
Date received	Apr 21, 1999
Decision date	Sep 13, 1999
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pacific Andrology, Inc.
Location	Irvine, CA, US
Contact	GREG HOLLAND
510(k) history	2 submissions · 2 cleared · 1999-1999

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k991388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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