

K081639 ICSI CUMULASESep 19, 2008
100 days to decisionK081639 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k081639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jun 11, 2008
Decision date	Sep 19, 2008
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medicult A/S
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	26 submissions · 26 cleared · 2000-2008

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