

**K080395 SUNIVF DISHES**Aug 13, 2008  
182 days to decisionK080395 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k080395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Feb 13, 2008
Decision date	Aug 13, 2008
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>&lt;Genx&gt; Intl., Inc.</b>
Location	Madison, CT, US
Contact	MICHAEL D CECCHI
510(k) history	32 submissions · 32 cleared · 1996-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080395/> 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 14, 2026