

**K013501 IUI, MODEL 4220**Nov 30, 2001  
39 days to decisionK013501 · Product code: **MQF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k013501/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Oct 22, 2001
Decision date	Nov 30, 2001
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement
Other names	SMOOZE, MODEL 4225, L; SEMINOR, MODEL 4502 A, B

**APPLICANT**

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Company	<b>Gynetics Medical Products NV</b>
Location	Irvine, CA, US
Contact	GRACE HOLLAND
510(k) history	4 submissions · 4 cleared · 2001-2004

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