

K013497 FAS SET #4551Nov 9, 2001
18 days to decisionK013497 · Product code: **MQE** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k013497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Oct 22, 2001
Decision date	Nov 9, 2001
Days to decision	18 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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