

K012068 WALLACE OOCYTE RETRIEVAL SETS 16G, WALLACE OOCYTE RETRIEVAL SET 17G, MODELS MEONS 1633S, MEONS 1733S

Aug 3, 2001
32 days to decision

K012068 · Product code: **MQE** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k012068/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Jul 2, 2001
Decision date	Aug 3, 2001
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sims Portex , Ltd.
Location	Hythe, Kent, GB
Contact	CLAIRE MULLINS
510(k) history	4 submissions · 4 cleared · 2000-2002

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Device record: <https://www.510kdatabase.net/k012068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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