

**K112644 SEAFORIA SPERM SEPARATION ASSISTANCE
SYSTEM**Dec 19, 2012
464 days to decisionK112644 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k112644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Sep 12, 2011
Decision date	Dec 19, 2012
Days to decision	464 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lotus Bio, Ltd.
Location	Pawtucket, RI, US
Contact	LORI KAHLER
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112644/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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