

K112396 IUI CATHETERSNov 2, 2012
441 days to decisionK112396 · Product code: **MQF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k112396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Aug 19, 2011
Decision date	Nov 2, 2012
Days to decision	441 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kitazato Medical Co., Ltd.
Location	Austin, TX, US
Contact	RICHARD VINCINS
510(k) history	3 submissions · 3 cleared · 2012-2013

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