

K131491 KITAZATO IUI CATHETERSep 11, 2013
111 days to decisionK131491 · Product code: **MQF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k131491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	May 23, 2013
Decision date	Sep 11, 2013
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131491/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026