

K150519 ManipulatOR PRO, ManipulatORAug 19, 2015
170 days to decisionK150519 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k150519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Mar 2, 2015
Decision date	Aug 19, 2015
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynetch Pty. , Ltd.
Location	Cincinnati, OH, US
Contact	Brett Telford
510(k) history	4 submissions · 4 cleared · 2005-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150519/> 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 4, 2026