FDA 510(k) Premarket Notification

K150519 ManipulatOR PRO, ManipulatOR

CLEARED

Aug 19, 2015
170 days to decision

K150519 · Product code: **LKF** · Obstetrics & Gynecology
Source: 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	**Gynetech Pty. , Ltd.**
Location	Cincinnati, OH, US
Contact	Brett Telford
510(k) history	4 submissions · 4 cleared · 2005-2015