

**K212505 DUMI ManipulatOR**Jan 10, 2022  
154 days to decisionK212505 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Aug 9, 2021
Decision date	Jan 10, 2022
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The O R Company Pty, Ltd.</b>
Location	Carrum Downs, AU
Contact	Amesha Silva
510(k) history	2 submissions · 2 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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