FDA 510(k) Premarket Notification

# K172846 Uterine Manipulator

**CLEARED**

Jun 26, 2018
280 days to decision

K172846 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k172846/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cannula, Manipulator/injector, Uterine (LKF) |
| Date received | Sep 19, 2017 |
| Decision date | Jun 26, 2018 |
| Days to decision | 280 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Beijing Hangtian Kadi Technology R&D Institute** |
| Location | Beijing, CN |
| Contact | Liying Zhang |
| 510(k) history | 2 submissions · 2 cleared · 2018-2018 |