

K180291 Cook Silicone Balloon HSG CatheterOct 26, 2018
267 days to decisionK180291 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k180291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Feb 1, 2018
Decision date	Oct 26, 2018
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Yan Li
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180291/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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