

K181770 Intrauterine Access Balloon Catheter, Selective Salpingography CatheterMar 29, 2019
269 days to decisionK181770 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Jul 3, 2018
Decision date	Mar 29, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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