FDA 510(k) Premarket Notification

K160217 uVue HSG/SHG Catheter

CLEARED

Oct 6, 2016
251 days to decision

K160217 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k160217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Jan 29, 2016
Decision date	Oct 6, 2016
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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