FDA 510(k) Premarket Notification

K220202 Uterine ElevatOR PRO with OccludOR Balloon

CLEARED

Mar 31, 2022
66 days to decision

K220202 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k220202/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Jan 24, 2022
Decision date	Mar 31, 2022
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**The O R Company Pty, Ltd.**
Location	Carrum Downs, AU
Contact	Nicole Conway
510(k) history	2 submissions · 2 cleared · 2022-2022