FDA 510(k) Premarket Notification

K974357 UTERINE MANIPULATOR/INJECTOR

CLEARED

Feb 2, 1998
75 days to decision

K974357 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k974357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Nov 19, 1997
Decision date	Feb 2, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Catheter Research, Inc.**
Location	Indianapolis, IN, US
Contact	JOHN A STEEN, PH.D.
510(k) history	8 submissions · 8 cleared · 1994-2013