FDA 510(k) Premarket Notification

K001115 ULTRA CATHETER SET

CLEARED

May 17, 2000
41 days to decision

K001115 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k001115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Apr 6, 2000
Decision date	May 17, 2000
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Lyco Enterprises, Inc.**
Location	El Paso, TX, US
Contact	ROBERT L CHILD
510(k) history	2 submissions · 2 cleared · 1995-2000