FDA 510(k) Premarket Notification

K083690 FEMVUE(TM) CATHETER SYSTEM

CLEARED

Jun 23, 2009
193 days to decision

K083690 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k083690/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Dec 12, 2008
Decision date	Jun 23, 2009
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Femasys, Inc.**
Location	Suwanee, GA, US
Contact	MARC FINCH
510(k) history	9 submissions · 9 cleared · 2009-2025