FDA 510(k) Premarket Notification

K110993 FEMCHEC PRESSURE MANAGEMET DEVICE

CLEARED

Oct 12, 2011
187 days to decision

K110993 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k110993/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Apr 8, 2011
Decision date	Oct 12, 2011
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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