

**K241693 FemChec Controlled Saline-Air Device (FCD-250)**Sep 6, 2024  
86 days to decisionK241693 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k241693/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Jun 12, 2024
Decision date	Sep 6, 2024
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Femasys, Inc.</b>
Location	Suwanee, GA, US
Contact	Christine Thomas
510(k) history	9 submissions · 9 cleared · 2009-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241693/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026