

K253403 FemVue® Controlled Saline-Air Device (FSA-300)Dec 15, 2025
76 days to decisionK253403 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k253403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Sep 30, 2025
Decision date	Dec 15, 2025
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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