

**K122658 FEMCERV ENDOCERVICAL SAMPLER MODEL 3
SIZES: REF FCV-013, REF FCV-011, REF FCV-009**Dec 20, 2012
111 days to decisionK122658 · Product code: **PCF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k122658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Endocervical (PCF)
Date received	Aug 31, 2012
Decision date	Dec 20, 2012
Days to decision	111 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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