

K131206 COOK CERVICAL RIPENING BALLOONSep 27, 2013
151 days to decisionK131206 · Product code: **PFJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k131206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Balloon, Dilation Of Cervical Canal Prior To Labor (PFJ)
Date received	Apr 29, 2013
Decision date	Sep 27, 2013
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook, Inc.
Location	Mchenry, IL, US
Contact	CHIRS KILANDER
510(k) history	190 submissions · 179 cleared · 1976-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131206/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026