

**K141322 ADVANCE ENFORCER 35 FOCAL FORCE PTA
BALLOON CATHETER**Mar 27, 2015
311 days to decisionK141322 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k141322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	May 20, 2014
Decision date	Mar 27, 2015
Days to decision	311 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	STEVEN LAWRIE
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141322/> 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 June 4, 2026