

**K132592 FLEXOR RADIAL HYDROPHILIC INTRODUCER
ACCESS SET**Oct 9, 2014
416 days to decisionK132592 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k132592/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 19, 2013
Decision date	Oct 9, 2014
Days to decision	416 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132592/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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