

K152044 Flexor Radial Hydrophilic Introducer Access SetAug 14, 2015
22 days to decisionK152044 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k152044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 23, 2015
Decision date	Aug 14, 2015
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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