

K153430 Flexor Tuohy-Borst Side-Arm Introducers Shuttle Select

Mar 7, 2016
103 days to decision

K153430 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k153430/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 25, 2015
Decision date	Mar 7, 2016
Days to decision	103 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k153430/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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