

K181592 RAIN Sheath TransradialAug 15, 2018
58 days to decisionK181592 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k181592/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 18, 2018
Decision date	Aug 15, 2018
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corporation
Location	Warren, NJ, US
Contact	Ankita Phophalia
510(k) history	13 submissions · 12 cleared · 2004-2022

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