

K191190 Steerable IntroducerAug 1, 2019
90 days to decisionK191190 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k191190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 3, 2019
Decision date	Aug 1, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Freudenberg Medical, LLC
Location	Jeffersonville, IN, US
Contact	Mary Prunty
510(k) history	3 submissions · 3 cleared · 2019-2024

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