

K183174 FlexCath Advance Steerable Sheath and DilatorNov 26, 2018
10 days to decisionK183174 · Product code: **DRA** · CardiovascularSource: <https://www.510kdatabase.net/k183174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Nov 16, 2018
Decision date	Nov 26, 2018
Days to decision	10 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Cryocath, LP
Location	Kirkland, CA
Contact	Natalie Sadeghi
510(k) history	6 submissions · 6 cleared · 2010-2020

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