

**K211110 Agile Devices Angler Steerable, Deflectable
Microcatheter**Jan 7, 2022
268 days to decisionK211110 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k211110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Apr 14, 2021
Decision date	Jan 7, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Agile Devices, Inc.
Location	Wellesley, MA, US
Contact	Stephen Tully
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Strategic Device Solutions, LLC
Contact	Stephen Tully

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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