

K210009 Guiding CatheterNov 24, 2021
324 days to decisionK210009 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k210009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 4, 2021
Decision date	Nov 24, 2021
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CenterPoint Systems, LLC
Location	West Valley City, UT, US
Contact	Marybeth Gamber
Website	https://centerpointsystems.com
510(k) history	12 submissions · 12 cleared · 2021-2026

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