

K213466 Houdini Cross Support CatheterOct 20, 2022
357 days to decisionK213466 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k213466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 28, 2021
Decision date	Oct 20, 2022
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cruzar Medsystems, Inc.
Location	Braintree, MA, US
Contact	Dave Tornatore
510(k) history	2 submissions · 2 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	Strategic Quality Solutions, LLC
Contact	Adrienne von Foller

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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