

K212165 Reprocessed Carto Vizigo Bi-Directional Guiding Sheath

Mar 10, 2022
241 days to decisionK212165 · Product code: **PNE** · Cardiovascular
Source: <https://www.510kdatabase.net/k212165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Jul 12, 2021
Decision date	Mar 10, 2022
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health, LLC
Location	Scottsdale, AZ, US
Contact	Rick Ferreira
510(k) history	48 submissions · 48 cleared · 2016-2024

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