

K221163 Tunnel Crossing CatheterJan 19, 2023
272 days to decisionK221163 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k221163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Apr 22, 2022
Decision date	Jan 19, 2023
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tractus Vascular, LLC
Location	Eatontown, NJ, US
Contact	Janet Burpee
510(k) history	3 submissions · 3 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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