

K203069 HydroMIDFeb 8, 2021
122 days to decisionK203069 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k203069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Oct 9, 2020
Decision date	Feb 8, 2021
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Access Vascular, Inc.
Location	Bedford, MA, US
Contact	Brian Hanley
510(k) history	9 submissions · 9 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203069/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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