FDA 510(k) Premarket Notification

K253168 0.014” Willow Guidewire

CLEARED

Nov 26, 2025
61 days to decision

K253168 · Product code: **MOF** · Neurology
Source: https://www.510kdatabase.net/k253168/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Sep 26, 2025
Decision date	Nov 26, 2025
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arbor Endovascular, LLC**
Location	San Jose, CA, US
Contact	Kim Otto
Website	https://arborvascular.com
510(k) history	4 submissions · 4 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**Fabrica Consulting, LLC**
Contact	Kathy Tansey

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov