

K250160 ANKYRASMay 6, 2025
105 days to decisionK250160 · Product code: **PZO** · Neurology
Source: <https://www.510kdatabase.net/k250160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Visualization Of Vascular Anatomy And Intravascular Devices (PZO)
Date received	Jan 21, 2025
Decision date	May 6, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mentice Spain S.L.
Location	Barcelona, ES
Contact	Héctor Fernández
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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