

K230006 AnkyrasDec 28, 2023
359 days to decisionK230006 · Product code: **PZO** · Neurology
Source: <https://www.510kdatabase.net/k230006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Visualization Of Vascular Anatomy And Intravascular Devices (PZO)
Date received	Jan 3, 2023
Decision date	Dec 28, 2023
Days to decision	359 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230006/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026