

K253122 Sim&SizeDec 23, 2025
89 days to decisionK253122 · Product code: **PZO** · Neurology
Source: <https://www.510kdatabase.net/k253122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Visualization Of Vascular Anatomy And Intravascular Devices (PZO)
Date received	Sep 25, 2025
Decision date	Dec 23, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sim&Cure
Location	Grabels, FR
Contact	Lucile Azema
510(k) history	6 submissions · 6 cleared · 2019-2025

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