

K231986 Modus IRMar 25, 2024
264 days to decisionK231986 · Product code: **IZI** · Neurology
Source: <https://www.510kdatabase.net/k231986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jul 5, 2023
Decision date	Mar 25, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synaptive Medical, Inc.
Location	Toronto On, CA
Contact	Tahmina Afzali
510(k) history	10 submissions · 10 cleared · 2014-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231986/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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