FDA 510(k) Premarket Notification

K251789 EMBOTRAP III Revascularization Device

CLEARED

Sep 25, 2025
106 days to decision

K251789 · Product code: **NRY** · Neurology
Source: https://www.510kdatabase.net/k251789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Jun 11, 2025
Decision date	Sep 25, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuravi Limited**
Location	Galway, IE
Contact	Marie Seoighe
510(k) history	3 submissions · 3 cleared · 2021-2025