FDA 510(k) Premarket Notification

K233791 Drivewire 24 Guidewire

CLEARED

Jul 11, 2024
226 days to decision

K233791 · Product code: **MOF** · Neurology
Source: https://www.510kdatabase.net/k233791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Nov 28, 2023
Decision date	Jul 11, 2024
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rapid Medical , Ltd.**
Location	Yokneam, IL
Contact	Ina Gutman
510(k) history	9 submissions · 7 cleared · 2019-2026