

K254006 Drivewire 35 Guidewire

Jul 17, 2026
214 days to decision

K254006 · Product code: MOF · Neurology
Source: <https://www.510kdatabase.net/k254006/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Dec 15, 2025
Decision date	Jul 17, 2026
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rapid Medical , Ltd.
Location	Yokneam, IL
Contact	Ina Gutman
510(k) history	10 submissions · 8 cleared · 2019-2026