FDA 510(k) Premarket Notification

K252011 CHIKAI Nexus petit

CLEARED

Feb 2, 2026
220 days to decision

K252011 · Product code: **MOF** · Neurology
Source: https://www.510kdatabase.net/k252011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Jun 27, 2025
Decision date	Feb 2, 2026
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Asahi Intecc Co., Ltd.**
Location	Seto-Shi, JP
Contact	Katsuhiko Fujimura
Website	https://www.asahi-intecc.com
510(k) history	83 submissions · 83 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	**Asahi Intecc USA, Inc.**
Contact	Ariel Barret

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov