

K253901 Millipede88 Access Catheter

Jul 9, 2026
216 days to decision

K253901 · Product code: QJP · Neurology
Source: <https://www.510kdatabase.net/k253901/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Dec 5, 2025
Decision date	Jul 9, 2026
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Perfuze, Ltd.
Location	Galway, IE
Contact	Jeanine O'Donnell
510(k) history	10 submissions · 10 cleared · 2022-2026