

K240971 87 NeuGlide CatheterDec 6, 2024
241 days to decisionK240971 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k240971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Apr 9, 2024
Decision date	Dec 6, 2024
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Piraeus Medical
Location	Maple Grove, MN, US
Contact	Jared Hutar
Website	https://www.piraeusmedical.com/
510(k) history	2 submissions · 2 cleared · 2024-2025

Piraeus Medical is a medical device company focused on Neurology devices. The company operates with a manufacturing facility in Maple Grove, Minnesota. Piraeus Medical has received FDA 510(k) clearances from total submissions. The company specializes exclusively in Neurology devices. Its regulatory activity spans from 2024 to 2025, demonstrating ongoing FDA engagement and recent market clearances. Recent cleared devices include catheter systems designed for neurological applications. The company maintains active regulatory status with clearances within the past two years....