

**K251044 93 NeuFlex Catheter**May 23, 2025  
50 days to decisionK251044 · Product code: **QJP** · Neurology  
Source: <https://www.510kdatabase.net/k251044/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Apr 3, 2025
Decision date	May 23, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Piraeus Medical</b>
Location	Maple Grove, MN, US
Contact	Jared Hutar
Website	<a href="https://www.piraeusmedical.com/">https://www.piraeusmedical.com/</a>
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....