FDA 510(k) Premarket Notification

CLEARED

K241637 Echo Intracranial Base Catheter

Dec 19, 2024
195 days to decision

K241637 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k241637/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Jun 7, 2024
Decision date	Dec 19, 2024
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Neurovascular**
Location	Freemont, CA, US
Contact	Shameena Segui
Website	https://www.stryker.com
510(k) history	32 submissions · 32 cleared · 2011-2026

Stryker Neurovascular is a medical device manufacturer based in Fremont, US. The company specializes in innovative interventional neurology solutions. Stryker Neurovascular has received FDA 510(k) clearances from total submissions since 2011. The company's portfolio is dominated by Neurology devices, representing 84% of regulatory submissions. The latest clearance was granted in 2026, demonstrating continued active development and market engagement. Recent cleared devices include intracranial base catheters, detachable coils, microcatheters, and thrombectomy retrievers. T...