

K193034 AXS Infinity LS Plus Long SheathNov 29, 2019
29 days to decisionK193034 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k193034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 31, 2019
Decision date	Nov 29, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Neurovascular
Location	Freemont, CA, US
Contact	Shivani H Patel
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...