FDA 510(k) Premarket Notification

K210502 Trevo NXT ProVue Retriever

CLEARED

Aug 27, 2021
186 days to decision

K210502 · Product code: **POL** · Neurology
Source: https://www.510kdatabase.net/k210502/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Feb 22, 2021
Decision date	Aug 27, 2021
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Neurovascular**
Location	Freemont, CA, US
Contact	Rebecca Rosman
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...

REGULATORY CONSULTANT

Consulting firm	**Stryker**
Contact	Ashley Twitty

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: https://www.510kdatabase.net/k210502/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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