FDA 510(k) Premarket Notification

CLEARED

K112385 TRAGET DETACHABLE COIL

Sep 15, 2011
28 days to decision

K112385 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k112385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Aug 18, 2011
Decision date	Sep 15, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Neurovascular**
Location	Freemont, CA, US
Contact	JAMES LEATHLEY
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...