FDA 510(k) Premarket Notification

CLEARED

K122576 TRANSFORM OCCLUSION BALLOON CATHETER (COMPLIANT AND SUPER COMPLIANT

Jan 11, 2013
141 days to decision

K122576 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k122576/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Aug 23, 2012
Decision date	Jan 11, 2013
Days to decision	141 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...