

**K183463 AXS Catalyst Distal Access Catheter 068 x 115cm,
AXS Catalyst Distal Access Catheter 068 x 125cm, AXS Catalyst
Distal Access Catheter 068 x 132cm**Mar 13, 2019
89 days to decisionK183463 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k183463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 14, 2018
Decision date	Mar 13, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker
Location	Portage, MI, US
Contact	Germaine Fu
Website	http://www.stryker.com/
510(k) history	92 submissions · 92 cleared · 2006-2023

Stryker is a family of eight-wheeled armored fighting vehicles derived from the Canadian LAV III. The vehicles are produced by General Dynamics Land Systems-Canada for the United States Army in London, Ontario. This historical record documents FDA 510(k) cleared devices from total submissions between 2006 and 2023. The company's regulatory portfolio focused primarily on General & Plastic Surgery devices, including advanced imaging systems, LED light sources, and surgical visualization equipment. The company has been inactive, with no clearances recorded in more than five ...