FDA 510(k) Premarket Notification

CLEARED

K190843 Synchro2 Support Guidewire

May 1, 2019
30 days to decision

K190843 · Product code: **MOF** · Neurology
Source: https://www.510kdatabase.net/k190843/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Apr 1, 2019
Decision date	May 1, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker**
Location	Portage, MI, US
Contact	Lorraine Mazzeo
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 ...