FDA 510(k) Premarket Notification

K111478 STRYKER SPINE POWER ADAPTOR (ACCESSORY INSTRUMENT)

CLEARED

Aug 4, 2011
69 days to decision

K111478 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k111478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 27, 2011
Decision date	Aug 4, 2011
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	TIFFANI ROGERS
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...