FDA 510(k) Premarket Notification

CLEARED

K070368 TRIO PLATE SYSTEM, TRIO SPINAL FIXATION SYSTEM, TRIO+ SPINAL SYSTEM

May 4, 2007
85 days to decision

K070368 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k070368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 8, 2007
Decision date	May 4, 2007
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	SIMONA VOIC
510(k) history	124 submissions · 121 cleared · 1976-2023

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...

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