

K121342 XIA 4.5 SPINAL SYSTEMJun 22, 2012
49 days to decisionK121342 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k121342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 4, 2012
Decision date	Jun 22, 2012
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corp.
Location	Mchenry, IL, US
Contact	TIFFANI ROGERS
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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