FDA 510(k) Premarket Notification

K091291 XIA 3 SPINAL SYSTEM, UNIPLANNER/REDUCTION SCREWS & VITALLIUM ROD

CLEARED

Jun 24, 2009
54 days to decision

K091291 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k091291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 1, 2009
Decision date	Jun 24, 2009
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Spine**
Location	Allendale, NJ, US
Contact	CURTIS TRUESDALE
510(k) history	74 submissions · 73 cleared · 2004-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091291/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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