CLEARED

Jun 8, 2023
275 days to decision

K222684 XIA® 4.5 Spinal System, XIA® 4.5 Cortical Trajectory, XIA® 3 Spinal System, Serrato® Spinal System, XIA® Growth Rod Conversion Set, XIA® II Spinal System, XIA® Precision System, XIA® Anterior, Diapason® Spinal System, Opus™ Spinal System, Radius® Spinal System, Mantis® Spinal System, Mantis® Redux, Trio® & Trio+ Spinal Fixation System, ES2™ Spinal System, ES2™ Augmentable Spinal System, Oasys® Occipito-Cervico-Thoracic System, Nile® Proximal Fixation Spinal System, Nile® Alternative Fi

K222684 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k222684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 6, 2022
Decision date	Jun 8, 2023
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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