FDA 510(k) Premarket Notification

K070631 DEVICE MODIFICATION TO RADIUS SPINAL SYSTEM

CLEARED

Jul 13, 2007
128 days to decision

K070631 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k070631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 7, 2007
Decision date	Jul 13, 2007
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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