

K113361 SECURIS SPINAL FIXATIONApr 3, 2012
141 days to decisionK113361 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k113361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 14, 2011
Decision date	Apr 3, 2012
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cumtomo Spine
Location	Parsippany, NJ, US
Contact	DAVID BRUMFIELD
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026