

K120829 STAINLESS STEEL SPINAL SYSTEMMay 30, 2012
72 days to decisionK120829 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k120829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 19, 2012
Decision date	May 30, 2012
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Theken Spine, LLC
Location	Akron, OH, US
Contact	DALE DAVISON
510(k) history	23 submissions · 23 cleared · 2007-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120829/> 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