

K100970 STAINLESS STEEL SPINAL SYSTEMAug 12, 2010
126 days to decisionK100970 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k100970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 8, 2010
Decision date	Aug 12, 2010
Days to decision	126 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

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