

**K070962 CORAL PEDICLE SCREW SYSTEM**Aug 22, 2007  
139 days to decisionK070962 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k070962/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 5, 2007
Decision date	Aug 22, 2007
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070962/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026