

**K080822 VU APOD INTERVERTABRAL BODY FUSION DEVICE**Jul 2, 2008  
100 days to decisionK080822 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k080822/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 24, 2008
Decision date	Jul 2, 2008
Days to decision	100 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/k080822/> 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