

K101310 VU APOD INTERVERTEBRAL BODY FUSION DEVICESep 2, 2010
114 days to decisionK101310 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k101310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 11, 2010
Decision date	Sep 2, 2010
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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