FDA 510(k) Premarket Notification

K082712 THEKEN SPINE VU EPOD AND VU LPOD SYSTEM

CLEARED

Jan 2, 2009
108 days to decision

K082712 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k082712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 16, 2008
Decision date	Jan 2, 2009
Days to decision	108 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.net
Device record: https://www.510kdatabase.net/k082712/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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