FDA 510(k) Premarket Notification

K080822 VU APOD INTERVERTABRAL BODY FUSION DEVICE

CLEARED

Jul 2, 2008
100 days to decision

K080822 · 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	**Theken Spine, LLC**
Location	Akron, OH, US
Contact	DALE DAVISON
510(k) history	23 submissions · 23 cleared · 2007-2012