FDA 510(k) Premarket Notification

K111166 A-WEDGE ANTERIOR INTERBODY SYSTEM (A-WEDGE A.I.S.)

CLEARED

Sep 8, 2011
135 days to decision

K111166 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k111166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 26, 2011
Decision date	Sep 8, 2011
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineworks, LLC**
Location	Washington, DC, US
Contact	J.D. WEBB
510(k) history	4 submissions · 4 cleared · 2005-2014