FDA 510(k) Premarket Notification

K100743 ATLAS SPINE PIVOTING SYSTEM

CLEARED

Aug 10, 2010
147 days to decision

K100743 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k100743/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 16, 2010
Decision date	Aug 10, 2010
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Atlas Spine, Inc.**
Location	Jupiter, FL, US
Contact	JEANNETTE G DAILEY
510(k) history	15 submissions · 15 cleared · 2007-2025