FDA 510(k) Premarket Notification

CLEARED

K180675 Atlas Spine Expandable Cervical Interbody System

Jun 13, 2018
90 days to decision

K180675 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k180675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 15, 2018
Decision date	Jun 13, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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