FDA 510(k) Premarket Notification

K152622 Alta ACDF System

CLEARED

Jul 8, 2016
298 days to decision

K152622 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k152622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 14, 2015
Decision date	Jul 8, 2016
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine**
Location	Warsaw, IN, US
Contact	ALEXANDRA BECK
510(k) history	19 submissions · 18 cleared · 2007-2016