

K153629 ArcadiusXP C Spinal SystemMay 25, 2016
159 days to decisionK153629 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k153629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Dec 18, 2015
Decision date	May 25, 2016
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant Systems, Inc.
Location	Center Valley, PA, US
Contact	Lisa M Boyle
510(k) history	22 submissions · 22 cleared · 2007-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153629/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026