FDA 510(k) Premarket Notification

K123909 AESCULAP CESPACE XP

CLEARED

Apr 15, 2013
117 days to decision

K123909 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k123909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 19, 2012
Decision date	Apr 15, 2013
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant System, Inc.**
Location	Center Valley, PA, US
Contact	LISA M BOYLE
510(k) history	18 submissions · 18 cleared · 2007-2014