FDA 510(k) Premarket Notification

K111122 AESCULAP SIBD XP SPINAL SYSTEM

CLEARED

Aug 4, 2011
105 days to decision

K111122 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k111122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Apr 21, 2011
Decision date	Aug 4, 2011
Days to decision	105 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