FDA 510(k) Premarket Notification

K083311 AESCULAP CESPACE PEEK INTERVERTEBRAL BODY FUSION SYSTEM

CLEARED

Mar 4, 2009
114 days to decision

K083311 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k083311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 10, 2008
Decision date	Mar 4, 2009
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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