FDA 510(k) Premarket Notification

CLEARED

K100802 AESCULAP IMPLANT SYSTEMS SIBD SPINAL SYSTEM

Jul 20, 2010
120 days to decision

K100802 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k100802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 22, 2010
Decision date	Jul 20, 2010
Days to decision	120 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