FDA 510(k) Premarket Notification

K090657 MODIFICATION TO: S4 SPINAL SYSTEM

CLEARED

Apr 20, 2009
39 days to decision

K090657 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k090657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 12, 2009
Decision date	Apr 20, 2009
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant Systems**
Location	Center Valley, PA, US
Contact	LISA M BOYLE
510(k) history	7 submissions · 7 cleared · 2007-2014