FDA 510(k) Premarket Notification

K090033 MODIFICATION TO: PSS SYSTEM

CLEARED

May 6, 2009
120 days to decision

K090033 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k090033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jan 6, 2009
Decision date	May 6, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal USA**
Location	Brandon, MS, US
Contact	JEFFREY JOHNSON
510(k) history	23 submissions · 23 cleared · 2006-2013