FDA 510(k) Premarket Notification

K081883 MODIFICATION TO PREFERENCE PEDICLE SCREW SYSTEM

CLEARED

Sep 24, 2008
84 days to decision

K081883 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k081883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jul 2, 2008
Decision date	Sep 24, 2008
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Us Spine**
Location	Apple Valley, MN, US
Contact	RICHARD JANSEN
510(k) history	5 submissions · 5 cleared · 2006-2008