FDA 510(k) Premarket Notification

K081790 MODIFICATION TO SINGLE PLANAR MULTI AXIS (SPMA) PEDICLE SCREW SYSTEM

CLEARED

Jul 24, 2008
29 days to decision

K081790 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k081790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jun 25, 2008
Decision date	Jul 24, 2008
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trinity Orthopedics, LLC**
Location	San Diego,, CA, US
Contact	KEVIN A THOMAS
510(k) history	2 submissions · 2 cleared · 2007-2008