FDA 510(k) Premarket Notification

K043522 ISSYS PEDICLE SCREW SYSTEM

CLEARED

Jan 14, 2005
25 days to decision

K043522 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k043522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Dec 20, 2004
Decision date	Jan 14, 2005
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Custom Spine, Inc.**
Location	Conway, NH, US
Contact	DEBBIE IAMPIETRO
510(k) history	12 submissions · 12 cleared · 2005-2015