FDA 510(k) Premarket Notification

K013312 P.L.U.S. SYSTEM (PIVOT LINK UNIVERSAL SYSTEM)

CLEARED

Feb 13, 2002
132 days to decision

K013312 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k013312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Oct 4, 2001
Decision date	Feb 13, 2002
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine Vision, Inc.**
Location	Good Hope, GA, US
Contact	LYNNETTE WHITAKER
510(k) history	12 submissions · 12 cleared · 2001-2005