FDA 510(k) Premarket Notification

K080526 SIERRA SYSTEM

CLEARED

Apr 16, 2008
50 days to decision

K080526 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k080526/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Feb 26, 2008
Decision date	Apr 16, 2008
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Seaspine, Inc.**
Location	Vista, CA, US
Contact	ETHEL BERNAL
510(k) history	27 submissions · 27 cleared · 2005-2023