FDA 510(k) Premarket Notification

K043152 VERTEBRON PSS PEDICLE SCREW SYSTEM

CLEARED

Feb 1, 2005
78 days to decision

K043152 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k043152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Nov 15, 2004
Decision date	Feb 1, 2005
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vertebron, Inc.**
Location	Stratford, CT, US
Contact	LUIS NESPRIDO
510(k) history	11 submissions · 11 cleared · 2004-2008