FDA 510(k) Premarket Notification

K133103 AVERSION PEDICLE SCREW SYSTEM

CLEARED

Jan 27, 2014
119 days to decision

K133103 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k133103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 30, 2013
Decision date	Jan 27, 2014
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K7, LLC**
Location	Chesterland, OH, US
Contact	KAREN E WARDEN
510(k) history	3 submissions · 3 cleared · 2013-2014