FDA 510(k) Premarket Notification

K133366 ORTHROS POSTERIOR STABILIZATION SYSTEM

CLEARED

Apr 8, 2014
158 days to decision

K133366 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k133366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 1, 2013
Decision date	Apr 8, 2014
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Camber Spine**
Location	Newtown Square, PA, US
Contact	DANIEL A PONTECORVO
510(k) history	4 submissions · 4 cleared · 2014-2015