FDA 510(k) Premarket Notification

K143683 APEX-DL Spine System

CLEARED

May 22, 2015
149 days to decision

K143683 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k143683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 24, 2014
Decision date	May 22, 2015
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinecraft, LLC**
Location	Westchester, IL, US
Contact	AMI AKALLAL-ASAAD
510(k) history	12 submissions · 12 cleared · 2010-2023