FDA 510(k) Premarket Notification

K180301 AXIS 5.5 Lumbar Pedicle Screw System

CLEARED

Apr 10, 2018
67 days to decision

K180301 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k180301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 2, 2018
Decision date	Apr 10, 2018
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Axis Orthopaedics**
Location	Soldotna, AK, US
Contact	Craig Wilcox
510(k) history	3 submissions · 3 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Coorstek Medical**
Contact	Steve Brown

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov