FDA 510(k) Premarket Notification

CLEARED

K181140 Axis Chena Cervical PEEK Spacer System

Nov 16, 2018
200 days to decision

K181140 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k181140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Apr 30, 2018
Decision date	Nov 16, 2018
Days to decision	200 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