FDA 510(k) Premarket Notification

CLEARED

K173867 Axis Anterior Cervical Plate System

Apr 5, 2018
106 days to decision

K173867 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k173867/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 20, 2017
Decision date	Apr 5, 2018
Days to decision	106 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