FDA 510(k) Premarket Notification

K190565 Cervical Plate

CLEARED

May 31, 2019
87 days to decision

K190565 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k190565/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 5, 2019
Decision date	May 31, 2019
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eisertech, LLC**
Location	San Diego, CA, US
Contact	Lukas Eisermann
510(k) history	8 submissions · 8 cleared · 2011-2019

REGULATORY CONSULTANT

Consulting firm	**Mrc-X, LLC**
Contact	Dawn Norman

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