FDA 510(k) Premarket Notification

K190016 Lateral Plate System

CLEARED

Jun 12, 2019
160 days to decision

K190016 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k190016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jan 3, 2019
Decision date	Jun 12, 2019
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corelink, LLC**
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**Empirical Consulting, LLC**
Contact	Meredith Lee May

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