FDA 510(k) Premarket Notification

K200523 Biolign® Roto-Loc Cervical Plate System

CLEARED

Apr 30, 2020
59 days to decision

K200523 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k200523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 2, 2020
Decision date	Apr 30, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Elite Surgical Supplies (Pty), Ltd.**
Location	Marietta, GA, US
Contact	Thanos Spirakis
510(k) history	4 submissions · 4 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Jordan Floyd

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