FDA 510(k) Premarket Notification

K220861 M6-C Artificial Cervical Disc Instruments AS

CLEARED

Jun 2, 2022
70 days to decision

K220861 · Product code: **QLQ** · Orthopedic
Source: https://www.510kdatabase.net/k220861/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Mar 24, 2022
Decision date	Jun 2, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Kinetics, LLC**
Location	Sunnyvale, CA, US
Contact	Joyce Zhong
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k220861/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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