K241117 M6-C™ Single Use, Disposable Instrumentation

CLEARED

Jun 21, 2024
59 days to decision

K241117 · Product code: **QLQ** · Orthopedic
Source: https://www.510kdatabase.net/k241117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Apr 23, 2024
Decision date	Jun 21, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Kinetics / Orthofix / Seaspine**
Location	Sunnyvale, CA, US
Contact	Tony John
510(k) history	1 submissions · 1 cleared · 2024-2024