FDA 510(k) Premarket Notification

CLEARED

K230840 PMT Facet Fixation System, Lumbar (PMT FFS-LX)

Dec 19, 2023
267 days to decision

K230840 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k230840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Mar 27, 2023
Decision date	Dec 19, 2023
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Providence Medical Technology, Inc.**
Location	Lafayette, CA, US
Contact	Edward Liou
510(k) history	19 submissions · 19 cleared · 2012-2025