FDA 510(k) Premarket Notification

K222515 FaSet Fixation System

CLEARED

Oct 5, 2022
47 days to decision

K222515 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k222515/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Aug 19, 2022
Decision date	Oct 5, 2022
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dio Medical Corporation**
Location	East Norriton, PA, US
Contact	Milan George
510(k) history	4 submissions · 4 cleared · 2022-2022