FDA 510(k) Premarket Notification

CLEARED

K232877 FaSet Fixation System, UNITY Sacroiliac Joint Fixation System, Huvex Interspinous Fixation System, and AEON-C™ Stand Alone System

Dec 13, 2023
89 days to decision

K232877 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k232877/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Sep 15, 2023
Decision date	Dec 13, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**K&J Consulting Corporation**
Location	Lansdale, PA, US
Contact	Milan George
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Eerkie Corporation**
Contact	Jeena Mathai

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