FDA 510(k) Premarket Notification

K243865 AERO MIS Facet Fusion System

CLEARED

Mar 24, 2025
97 days to decision

K243865 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k243865/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Dec 17, 2024
Decision date	Mar 24, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aurora Spine**
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	3 submissions · 3 cleared · 2013-2025

REGULATORY CONSULTANT

Consulting firm	**Medical Device Development**
Contact	Jeremi Leasure

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