FDA 510(k) Premarket Notification

K230851 Kodiak Lumbar Spacer System

CLEARED

May 26, 2023
59 days to decision

K230851 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k230851/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 28, 2023
Decision date	May 26, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Met One Technologies, LLC**
Location	El Paso, TX, US
Contact	Adrian Carbonell
510(k) history	4 submissions · 4 cleared · 2022-2026