FDA 510(k) Premarket Notification

K223335 SIRION Lateral Lumbar Interbody System

CLEARED

May 9, 2023
189 days to decision

K223335 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 1, 2022
Decision date	May 9, 2023
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Astura Medical**
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	21 submissions · 21 cleared · 2016-2026