FDA 510(k) Premarket Notification

CLEARED

K223065 Adcura® Sagittae® Lateral Lumbar Interbody Fusion Devices

Oct 26, 2022
26 days to decision

K223065 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 30, 2022
Decision date	Oct 26, 2022
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Adcura, Inc.**
Location	Eden Prairie, MN, US
Contact	Andrew Rogers
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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