FDA 510(k) Premarket Notification

CLEARED

K231199 Solar Lumbar Interbody Fusion System

Jun 16, 2023
50 days to decision

K231199 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k231199/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 27, 2023
Decision date	Jun 16, 2023
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Degen Medical**
Location	Florence, SC, US
Contact	Craig Black
510(k) history	16 submissions · 16 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Justin Gracyalny

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k231199/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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