FDA 510(k) Premarket Notification

CLEARED

K212389 Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF

Oct 29, 2021
88 days to decision

K212389 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k212389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 2, 2021
Decision date	Oct 29, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intelivation, LLC**
Location	Saint Simons Island, GA, US
Contact	Amit Sinha
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**RQMIS, Inc.**
Contact	Barry Sands

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