FDA 510(k) Premarket Notification

K223418 DeGen Impulse AM™ System

CLEARED

Mar 17, 2023
127 days to decision

K223418 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 10, 2022
Decision date	Mar 17, 2023
Days to decision	127 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	Linda Braddon

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