

K210090 Impulse AM Interbody Fusion SystemAug 30, 2021
229 days to decisionK210090 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k210090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 13, 2021
Decision date	Aug 30, 2021
Days to decision	229 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210090/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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