

K250667 DeGen Medical Patient Specific Implant (PSI) SystemApr 4, 2025
30 days to decisionK250667 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k250667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 5, 2025
Decision date	Apr 4, 2025
Days to decision	30 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.netDevice record: <https://www.510kdatabase.net/k250667/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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