

K251829 DeGen Medical Patient Specific Implant (PSI) SystemDec 8, 2025
178 days to decisionK251829 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k251829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jun 13, 2025
Decision date	Dec 8, 2025
Days to decision	178 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/k251829/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026