

K241077 DeGen Medical Patient Specific Implant (PSI) SystemOct 29, 2024
193 days to decisionK241077 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k241077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Apr 19, 2024
Decision date	Oct 29, 2024
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Degen Medical
Location	Florence, SC, US
Contact	Black Craig
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

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