FDA 510(k) Premarket Notification

K253894 BMD Titanium Spinal Fusion System

CLEARED

May 28, 2026
175 days to decision

K253894 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k253894/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 4, 2025
Decision date	May 28, 2026
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Global Biomedica s.r.o.**
Location	Český Těšín, CZ
Contact	Piotr Koziel
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert Poggie

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