

K221542 Galileo Vertebral Body Replacement DeviceJan 13, 2023
231 days to decisionK221542 · Product code: **PLR** · Orthopedic
Source: <https://www.510kdatabase.net/k221542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinal Vertebral Body Replacement Device - Cervical (PLR)
Date received	May 27, 2022
Decision date	Jan 13, 2023
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bright Spine
Location	Boca Raton, FL, US
Contact	Robert Simonson
510(k) history	2 submissions · 2 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Lighthouse Regulatory Consulting Group
Contact	Bahram Parvinian

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221542/> 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 27, 2026