

K193412 NEXXT MATRIX SystemFeb 24, 2020
77 days to decisionK193412 · Product code: **PLR** · Orthopedic
Source: <https://www.510kdatabase.net/k193412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device - Cervical (PLR)
Date received	Dec 9, 2019
Decision date	Feb 24, 2020
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nexxt Spine, LLC
Location	Chesterland, OH, US
Contact	Andy Elsbury
510(k) history	22 submissions · 22 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	Backroads Consulting
Contact	Karen E Warden

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/k193412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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