

**K191423 Normandy VBR System**Aug 6, 2019  
69 days to decisionK191423 · Product code: **PLR** · Orthopedic  
Source: <https://www.510kdatabase.net/k191423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device - Cervical (PLR)
Date received	May 29, 2019
Decision date	Aug 6, 2019
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zavation Medical Products, LLC</b>
Location	Flowood, MS, US
Contact	Frankie Cummins
510(k) history	30 submissions · 30 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191423/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026