

**K223231 Ti-Largo Cervical Interbody System**Feb 24, 2023  
129 days to decisionK223231 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k223231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Oct 18, 2022
Decision date	Feb 24, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Flospine</b>
Location	Fr. Myers, FL, US
Contact	Peter Harris
510(k) history	4 submissions · 4 cleared · 2014-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>BioVera, Inc.</b>
Contact	Robert A Poggie

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

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