

**K243814 NuVasive Pulse System**Jan 10, 2025  
30 days to decisionK243814 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243814/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 11, 2024
Decision date	Jan 10, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Globus Medical, Inc.</b>
Location	Audubon, PA, US
Contact	Prem Kumar Pisupati
Website	<a href="https://www.globusmedical.com">https://www.globusmedical.com</a>
510(k) history	171 submissions · 168 cleared · 2003-2026

Globus Medical, Inc. is a publicly traded orthopedic medical device company headquartered in Audubon, Pennsylvania. The company designs, develops, and commercializes products enabling surgeons to promote healing in patients with musculoskeletal disorders. Globus Medical has received FDA 510(k) clearances from total submissions since its first clearance in 2003. The company's regulatory portfolio is dominated by orthopedic devices, representing 98% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued innovation and market presenc...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nu Vasive, Incorporated</b>
Contact	Prem Pisupati

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243814/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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