

**K171413 HAVEN™ Laminoplasty System, CANOPY®  
Laminoplasty Fixation System**Jul 14, 2017  
60 days to decisionK171413 · Product code: **NQW** · Orthopedic  
Source: <https://www.510kdatabase.net/k171413/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	May 15, 2017
Decision date	Jul 14, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Globus Medical, Inc.</b>
Location	Audubon, PA, US
Contact	Kelly J. Baker
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...

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

Device record: <https://www.510kdatabase.net/k171413/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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