

**K151939 COALITION Spacers**Jan 29, 2016  
199 days to decisionK151939 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k151939/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE) |
| Date received         | Jul 14, 2015  |
| Decision date         | Jan 29, 2016  |
| Days to decision      | 199 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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