

K160597 INDEPENDENCE MIS SpacersAug 29, 2016
180 days to decisionK160597 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k160597/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Mar 2, 2016 |
| Decision date | Aug 29, 2016 |
| Days to decision | 180 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Globus Medical, Inc. |
| Location | Audubon, PA, US |
| Contact | Kelly J. Baker |
| Website | https://www.globusmedical.com |
| 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...
