

**K222270 HEDRON Cervical Spacers, HEDRON Lumbar Spacers,
SABLE Expandable Spacer, ExcelsiusGPS Instruments**Oct 21, 2022
84 days to decisionK222270 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k222270/>**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 | Jul 29, 2022 |
| Decision date | Oct 21, 2022 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Globus Medical, Inc. |
| Location | Audubon, PA, US |
| Contact | Kelly 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...