

K133678 CONFIRM BIOACTIVEAug 26, 2014
270 days to decisionK133678 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k133678/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Nov 29, 2013 |
| Decision date | Aug 26, 2014 |
| Days to decision | 270 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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