FDA 510(k) Premarket Notification

**CLEARED**

# K221737 InstaFill Graft Delivery System, SIGNIFY Bioactive

Aug 11, 2022
57 days to decision

K221737 · Product code: **FMF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221737/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Jun 15, 2022 |
| Decision date | Aug 11, 2022 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

**APPLICANT**

| | |
|---|---|
| Company | **Globus Medical, Inc.** |
| Location | Audubon, PA, US |
| Contact | Jennifer Antonacci |
| 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...