

K073341 GENEX PUTTYJul 9, 2008
224 days to decisionK073341 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k073341/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Nov 28, 2007 |
| Decision date | Jul 9, 2008 |
| Days to decision | 224 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biocomposites, Ltd. |
| Location | Keele, GB |
| Contact | SIMON FITZER |
| Website | https://www.biocomposites.com |
| 510(k) history | 27 submissions · 27 cleared · 2000-2026 |

Biocomposites, Ltd. is an international medical device manufacturer based in Keele, GB. The company engineers and manufactures specialized devices for musculoskeletal infection, trauma, spine, and orthopedic applications. Biocomposites has received FDA 510(k) clearances from total submissions since 2000. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, confirming active regulatory engagement. The company's core product lines include antibiotic-loaded bone cem...
