

K193061 G3 40 Radiopaque Bone CementMar 19, 2020
139 days to decisionK193061 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k193061/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Cement (LOD) |
| Date received | Nov 1, 2019 |
| Decision date | Mar 19, 2020 |
| Days to decision | 139 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | G21, S.R.L. |
| Location | San Possidonio, IT |
| Contact | Filippo Foroni |
| 510(k) history | 12 submissions · 12 cleared · 2015-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026