

K092773 CEMEX GENTA, GENTA SYSTEM AND GENTA SYSTEM FASTNov 24, 2009
76 days to decisionK092773 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k092773/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Bone Cement (LOD) |
| Date received | Sep 9, 2009 |
| Decision date | Nov 24, 2009 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tecres S.P.A. |
| Location | Bethesda, MD, US |
| Contact | CHRISTINE BRAUER |
| 510(k) history | 14 submissions · 14 cleared · 2005-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092773/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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