

K211163 Bone Cement Genta, Bone Cement HV, Bone Cement LVJan 9, 2023
630 days to decisionK211163 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k211163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Apr 19, 2021
Decision date	Jan 9, 2023
Days to decision	630 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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