

K122175 MENDEC SPINE HV, MENDEC SPINE HV SYSTEMMar 28, 2013
248 days to decisionK122175 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k122175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jul 23, 2012
Decision date	Mar 28, 2013
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122175/> 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