

K042415 MENDEC SPINEJun 9, 2005
275 days to decisionK042415 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k042415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 7, 2004
Decision date	Jun 9, 2005
Days to decision	275 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/k042415/> 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