

K043593 SPINE-FIX BIOMIMETIC BONE CEMENTMar 17, 2006
443 days to decisionK043593 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k043593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Dec 29, 2004
Decision date	Mar 17, 2006
Days to decision	443 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teknimed, S.A.
Location	Round Rock, TX, US
Contact	J. D. WEBB
510(k) history	11 submissions · 11 cleared · 2003-2011

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