

**K080873 OPACITY + BONE CEMENT**Aug 28, 2008  
150 days to decisionK080873 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k080873/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Mar 31, 2008
Decision date	Aug 28, 2008
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080873/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026