

**K061531 SPACE CPSXL BONE CEMENT**Aug 30, 2006  
89 days to decisionK061531 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k061531/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 2, 2006
Decision date	Aug 30, 2006
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dfine, Inc.</b>
Location	Cupertino, CA, US
Contact	ROBERT D POSER
510(k) history	5 submissions · 5 cleared · 2006-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061531/> 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 19, 2026