

**K041584 KYPHX HV-R BONE CEMENT, MODEL C01A**Jul 7, 2004  
23 days to decisionK041584 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k041584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 14, 2004
Decision date	Jul 7, 2004
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kyphon, Inc.</b>
Location	Sunnyvale, CA, US
Contact	CINDY DOMECUS
510(k) history	9 submissions · 9 cleared · 1998-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041584/> 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 20, 2026