

**K042591 SMARTMIX PRE-FILLED MIXING SYSTEM**Oct 22, 2004  
29 days to decisionK042591 · Product code: **KIH** · Orthopedic  
Source: <https://www.510kdatabase.net/k042591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dispenser, Cement (KIH)
Date received	Sep 23, 2004
Decision date	Oct 22, 2004
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DePuy Orthopaedics, Inc.</b>
Location	Warsaw, IN, US
Contact	TIFFANI ROGERS
510(k) history	206 submissions · 204 cleared · 1998-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042591/> 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 26, 2026