

**K012045 HIGHGATE CURVED ROD SYSTEM**Mar 12, 2002  
256 days to decisionK012045 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k012045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 29, 2001
Decision date	Mar 12, 2002
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Highgate Orthopaedics</b>
Location	Chesterland, OH, US
Contact	KAREN E WARDEN
510(k) history	2 submissions · 2 cleared · 2002-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012045/> 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