

**K070335 SIMPLEX CERVICAL FIXATION SYSTEM**Apr 16, 2007  
70 days to decisionK070335 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k070335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 5, 2007
Decision date	Apr 16, 2007
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pisharodi Surgicals, Inc.</b>
Location	Brownsville, TX, US
Contact	J.D. WEBB
510(k) history	4 submissions · 4 cleared · 2002-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070335/> 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