

**K010466 TETHER ACFS**May 16, 2001  
89 days to decisionK010466 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k010466/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 16, 2001
Decision date	May 16, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Theken Surgical,Llc</b>
Location	Barberton, OH, US
Contact	ROBERT THEKEN
510(k) history	6 submissions · 4 cleared · 1998-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010466/> 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