

**K161809 ShurFit CpTi-HA ACIF Interbody Fusion System**Dec 6, 2016  
158 days to decisionK161809 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k161809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 1, 2016
Decision date	Dec 6, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Precision Spine, Inc.</b>
Location	Pear, MS, US
Contact	Michael C. Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161809/> 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 16, 2026